EXHIBIT N

Page 1

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP., MDL NO.: 2326

PELVIC REPAIR SYSTEM

PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

Chapa v. Boston Scientific Corporation 2:13-cv-17511

Fisher v. Boston Scientific Corporation 2:13-cv-29324

Flandro v. Boston Scientific Corporation 2:13-cv-17027

Toronto, Ontario, Canada
Wednesday, December 17, 2014
VOLUME I

Videotaped Deposition of VLADIMIR IAKOVLEV,
M.D., a witness herein, called for examination
by counsel for the Defendants in the above-mentioned
matter, the witness having been affirmed, taken at the
offices of Neesons Reporting, 141 Adelaide Street West,
Toronto, Ontario, at 9:11 a.m., on Wednesday, December 17,
2014, and the proceedings being taken down by Stenotype
and transcribed by JUDITH M. CAPUTO, RPR, CSR, CRR.

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4	Franco v. Boston Scientific Corporation 2:12-cv-07248	4 BY: CRAIG EILAND, ESQ.	·
5	Hanson v. Boston Scientific Corporation 2:13-cv-10653	5 Law Offices of Craig Eiland	
6	Hoffman v. Boston Scientific Corporation 2:12-cv-04433	6 2211 The Strand, Suite 201	
7	Howard v. Boston Scientific Corporation 2:12-cv-04145	7 Galveston, Texas 77550	
8	Kilgore v. Boston Scientific Corporation 2:13-cv-09171	8 409.763.3260	
9	Parker v. Boston Scientific Corporation 2:12-cv-01243	9	
10	Reynolds v. Boston Scientific Corporation 2:12-cv-09934	10 ON BEHALF OF THE DEFENDAN	JTS:
11	Robbins v. Boston Scientific Corporation 2:12-cv-01413	11 BY: ADRIENNE L. BYARD, ESQ.	
12	Tame v. Boston Scientific Corporation 2:13-cv-01059	12 Shook, Hardy & Bacon, LLP	
13	Watanabe v. Boston Scientific Corporation 2:13-cv-12227	13 2555 Grand Boulevard	
14	······································	14 Kansas City, Missouri 64108	
15		15 816.474.6550	
16	APPEARANCES:	16	
17		17 ALSO PRESENT:	
18	ON BEHALF OF THE PLAINTIFFS:	18 DENNIS COSTIGAN, Motley Rice	LLC
19	BY: JONATHAN D. ORENT, ESQ.	19	LLC
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23	401.457.7723	23	
24	101.137.7723	24	
25		25	
20			
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A P P E A R A N C E S: ON BEHALF OF THE PLAINTIFFS: BY: ALAN S. LAZAR, ESQ. Marlin Saltzman, LLP 29229 Canwood Street, Suite 208 Agoura Hills, California 91301 818.991.8080 ON BEHALF OF THE PLAINTIFFS: BY: NATHAN C. BESS, ESQ. Aylstock, Witkin, Kreis & Overholtz 17 East Main Street, Suite 200 Pensacola, Florida 32502 850.202.1010 ON BEHALF OF THE PLAINTIFFS: BY: KATY KROTTINGER, ESQ. The Monsour Law Firm 404 North Green Street Longview, Texas 75606	1 INDEX 2 3 WITNESS: VLADIMIR IAKOVLEV, M.D. 4 PAGE 5 DIRECT EXAMINATION BY MS. BYARD	8

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1	1198: International Scholarly and 156	1	Defendant, Boston Scientific.
2	Scientific Research & Innovation, 2014,	2	MR. EILAND: Craig Eiland for the
3	Publication entitled, "Pathology of	3	Plaintiffs.
4	Explanted Transvaginal Meshes," by	4	THE VIDEOGRAPHER: Thank you.
5	Dr. V. Iakovlev, Dr. E. T. Carey and	5	The court reporter is Judy Caputo, CSR,
6	Dr. J. Steege.	6	and who will now swear in or affirm the witness.
7	1199: Abstract entitled, "Pathological 186	7	Whereupon,
8	Findings of Transvaginal Polypropylene	8	VLADIMIR IAKOVLEV, M.D.,
9	Slings Explanted for Late Complications:	9	called for examination by counsel for Defendants
10	Mesh is Not Inert," by Dr. V. Iakovlev,	10	and having been affirmed by me, was examined and
11	Dr. G. Mekel and Dr. J. Blaivas.	11	testified as follows:
12	1201: Abstract entitled, "In-vivo 207	12	DIRECT EXAMINATION BY MS. BYARD:
13	Degradation of Surgical Polypropylene	13	Q. Dr. Iakovlev, it's very nice to
14	Meshes: A Finding Overlooked for	14	see you again. You'll recall I'm Adrienne Byard.
15	Decades," by Dr. V. Iakovlev,	15	I think the last time we had the opportunity to
16	Dr. S. Guelcher, Dr. R. Bendavid.	16	talk was in January of 2014, when I took your
17	Bit S. Guelener, Bit R. Bendavia.	17	deposition here in Toronto. Do you remember that
18		18	deposition?
19		19	A. Yes, I do.
20		20	Q. And since that time you've been
21		21	deposed again; correct?
22		22	A. By Boston Scientific, yes.
23		23	Q. And also by other mesh
24		24	manufacturers, right?
25		25	A. Yes, that's correct.
23		23	A. Tes, that's correct.
	Page 7		Page 9
1	Upon commencing at 9:11 a.m.	1	Q. Okay. And you've also had the
2		2	opportunity to testify at some trials; correct?
3	THE VIDEOGRAPHER: Good morning. We	3	A. Yes.
4	are now on the record. My name is Peter Goodale,	4	Q. Let's work forwards in time.
5	certified legal videographer for Golkow Technologies.	5	So from January 2014, when I took your
6	Today's date is December 17, 2014, and	6	deposition here in Toronto, when was your next
7	the time on the video monitor is 9:11 a.m.	_	
^		7	deposition?
8	This video deposition is being held in	8	deposition? A. I think I had one, either in
8 9	This video deposition is being held in Toronto, Ontario, Canada in the matter of: In Re:		
	1 6	8	A. I think I had one, either in
9	Toronto, Ontario, Canada in the matter of: In Re:	8 9	A. I think I had one, either in February, February 4th or somewhere in that date,
9 10	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System	8 9 10	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March
9 10 11	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United	8 9 10 11	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you
9 10 11 12	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of	8 9 10 11 12	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you don't mind. Were those in an AMS matter?
9 10 11 12 13	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326.	8 9 10 11 12 13	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you don't mind. Were those in an AMS matter? A. Yes.
9 10 11 12 13 14	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326. The deponent is Dr. Vladimir Iakovlev.	8 9 10 11 12 13 14	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you don't mind. Were those in an AMS matter? A. Yes. Q. And just one, one case, right?
9 10 11 12 13 14 15	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326. The deponent is Dr. Vladimir Iakovlev. Counsel, please identify yourselves and state who	8 9 10 11 12 13 14 15	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you don't mind. Were those in an AMS matter? A. Yes. Q. And just one, one case, right? A. What do you mean "one case"?
9 10 11 12 13 14 15	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326. The deponent is Dr. Vladimir Iakovlev. Counsel, please identify yourselves and state who you represent.	8 9 10 11 12 13 14 15 16	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you don't mind. Were those in an AMS matter? A. Yes. Q. And just one, one case, right? A. What do you mean "one case"? Q. Was it just were you just
9 10 11 12 13 14 15 16	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326. The deponent is Dr. Vladimir Iakovlev. Counsel, please identify yourselves and state who you represent. MR. ORENT: Jonathan Orent for the	8 9 10 11 12 13 14 15 16	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you don't mind. Were those in an AMS matter? A. Yes. Q. And just one, one case, right? A. What do you mean "one case"? Q. Was it just were you just looking at pathological specimens for a single
9 10 11 12 13 14 15 16 17	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326. The deponent is Dr. Vladimir Iakovlev. Counsel, please identify yourselves and state who you represent. MR. ORENT: Jonathan Orent for the Plaintiffs.	8 9 10 11 12 13 14 15 16 17 18	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you don't mind. Were those in an AMS matter? A. Yes. Q. And just one, one case, right? A. What do you mean "one case"? Q. Was it just were you just looking at pathological specimens for a single case, or were your opinions applying across
9 10 11 12 13 14 15 16 17 18	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326. The deponent is Dr. Vladimir Iakovlev. Counsel, please identify yourselves and state who you represent. MR. ORENT: Jonathan Orent for the Plaintiffs. MR. LAZAR: Alan Lazar for the	8 9 10 11 12 13 14 15 16 17 18	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you don't mind. Were those in an AMS matter? A. Yes. Q. And just one, one case, right? A. What do you mean "one case"? Q. Was it just were you just looking at pathological specimens for a single case, or were your opinions applying across AMS cases; if you know? A. There were a number of cases.
9 10 11 12 13 14 15 16 17 18 19 20	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326. The deponent is Dr. Vladimir Iakovlev. Counsel, please identify yourselves and state who you represent. MR. ORENT: Jonathan Orent for the Plaintiffs. MR. LAZAR: Alan Lazar for the Plaintiffs.	8 9 10 11 12 13 14 15 16 17 18 19 20	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you don't mind. Were those in an AMS matter? A. Yes. Q. And just one, one case, right? A. What do you mean "one case"? Q. Was it just were you just looking at pathological specimens for a single case, or were your opinions applying across AMS cases; if you know? A. There were a number of cases. Q. Okay. And then when was your
9 10 11 12 13 14 15 16 17 18 19 20 21	Toronto, Ontario, Canada in the matter of: In Re: Boston Scientific Corporation Pelvic Repair System Products Liability Litigation, for the United States District Court, for the Southern District of West Virginia, Charleston Division, MDL No. 2326. The deponent is Dr. Vladimir Iakovlev. Counsel, please identify yourselves and state who you represent. MR. ORENT: Jonathan Orent for the Plaintiffs. MR. LAZAR: Alan Lazar for the Plaintiffs. MR. BESS: Nathan Bess, also for the Plaintiffs.	8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I think I had one, either in February, February 4th or somewhere in that date, and there was another one in March Q. Let me stop you there, if you don't mind. Were those in an AMS matter? A. Yes. Q. And just one, one case, right? A. What do you mean "one case"? Q. Was it just were you just looking at pathological specimens for a single case, or were your opinions applying across AMS cases; if you know? A. There were a number of cases. Q. Okay. And then when was your next deposition?
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	Page 10		Page 12
1	A. Then there was one for Ethicon in	1	Q. You said "my obligations"?
2	April.	2	A. No, no, I didn't say that.
3	Q. Okay.	3	Q. Oh, really? Okay, I missed it
4	A. But that's not a memory test. The	4	then. Somewhere between "medical records reviewed
5	recent depositions is provided on the flash drive	5	for Plaintiffs" and the "billing for Plaintiffs"
6	for you.	6	MR. ORENT: He said "publications."
7	Q. Okay. So you've brought some	7	BY MS. BYARD:
8	materials with you here today through counsel in	8	Q. "Publications." Publications,
9	response to our request. Is that what you're	9	thank you so much.
10	saying?	10	You'll remember the rules of the
11	A. That's correct.	11	deposition, I'm sure, that if there are times when
12	Q. Okay. And we'll go ahead and mark	12	we don't understand each other, I'll ask for
13	as 1195, the Notice of Deposition. I'll pass a	13	clarification and I'll ask that you do the same;
14	copy of that to you.	14	all right?
15	EXHIBIT NO. 1195: Notice of Videotaped	15	A. Sure.
16	Deposition Duces Tecum of Dr. Vladimir	16	Q. If you don't ask for
17	Iakovlev.	17	clarification, I'll assume you understood me, okay?
18	BY MS. BYARD:	18	A. (Witness nods).
19	Q. Is this deposition notice, or one	19	Q. Is that fair?
20	similar to it, familiar to you, sir?	20	A. Yes, that's fair.
21	A. Yes.	21	Q. Very good.
22	Q. And did you bring documents	22	What else was, besides your
23	responsive to our request through counsel?	23	publications, the medical records you reviewed for
24	A. Yes.	24	Plaintiffs, and the billings for Plaintiffs, is on
25	Q. What were the documents, as far as	25	that thumb drive, so far as you know?
	Page 11		Page 13
1	you understand it, that were being brought here	1	A. The list of testimonies I gave.
2	today in response to our request?	2	Q. Okay.
3	A. Medical records I reviewed for the	3	A. My current CV.
4	Plaintiffs. My publications, billing I produced	4	Q. You don't have a paper copy of
5	for the Plaintiffs, which were identified in this	5	that that I could review and go over with you now
6	notice.	6	of any of those materials?
7	Q. Okay.	7	A. No, I didn't bring them. I tried
8	A. For whatever reason, there is no	8	to save trees.
9	list here. It looks different than what I	9	Q. Okay. Well, we'll take that up on
10	received.	10	a break.
	Q. Right. The list you saw, and I'll	11	I want to notum to this list of
11			I want to return to this list of
12	just show you this we're not going to mark it at	12	depositions. So you gave a deposition in April or
12 13	just show you this we're not going to mark it at this point but it was a longer list like this,	12 13	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given
12 13 14	just show you this we're not going to mark it at this point but it was a longer list like this, right?	12 13 14	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other
12 13 14 15	just show you this we're not going to mark it at this point but it was a longer list like this, right? A. Yes. That looks more familiar	12 13 14 15	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other manufacturers of transvaginal mesh?
12 13 14 15 16	just show you this we're not going to mark it at this point but it was a longer list like this, right? A. Yes. That looks more familiar than this.	12 13 14 15 16	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other manufacturers of transvaginal mesh? A. Yes.
12 13 14 15 16 17	just show you this we're not going to mark it at this point but it was a longer list like this, right? A. Yes. That looks more familiar than this. Q. Okay. And so you brought the	12 13 14 15 16 17	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other manufacturers of transvaginal mesh? A. Yes. Q. Okay. Which others?
12 13 14 15 16 17	just show you this we're not going to mark it at this point but it was a longer list like this, right? A. Yes. That looks more familiar than this. Q. Okay. And so you brought the billing that pertained to those women's cases,	12 13 14 15 16 17 18	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other manufacturers of transvaginal mesh? A. Yes. Q. Okay. Which others? A. Bard.
12 13 14 15 16 17 18 19	just show you this we're not going to mark it at this point but it was a longer list like this, right? A. Yes. That looks more familiar than this. Q. Okay. And so you brought the billing that pertained to those women's cases, right?	12 13 14 15 16 17 18 19	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other manufacturers of transvaginal mesh? A. Yes. Q. Okay. Which others? A. Bard. Q. When was that deposition?
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12 13 14 15 16 17 18 19 20 21	just show you this we're not going to mark it at this point but it was a longer list like this, right? A. Yes. That looks more familiar than this. Q. Okay. And so you brought the billing that pertained to those women's cases, right? A. Um-hum. Q. Okay.	12 13 14 15 16 17 18 19 20 21	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other manufacturers of transvaginal mesh? A. Yes. Q. Okay. Which others? A. Bard. Q. When was that deposition? A. Let me turn it up. The deposition for Bard was in November.
12 13 14 15 16 17 18 19 20 21	just show you this we're not going to mark it at this point but it was a longer list like this, right? A. Yes. That looks more familiar than this. Q. Okay. And so you brought the billing that pertained to those women's cases, right? A. Um-hum. Q. Okay. A. Yes.	12 13 14 15 16 17 18 19 20 21	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other manufacturers of transvaginal mesh? A. Yes. Q. Okay. Which others? A. Bard. Q. When was that deposition? A. Let me turn it up. The deposition for Bard was in November. Q. November. Now you've also
12 13 14 15 16 17 18 19 20 21 22 23	just show you this we're not going to mark it at this point but it was a longer list like this, right? A. Yes. That looks more familiar than this. Q. Okay. And so you brought the billing that pertained to those women's cases, right? A. Um-hum. Q. Okay. A. Yes. Q. Now, when you say "obligations,"	12 13 14 15 16 17 18 19 20 21 22 23	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other manufacturers of transvaginal mesh? A. Yes. Q. Okay. Which others? A. Bard. Q. When was that deposition? A. Let me turn it up. The deposition for Bard was in November. Q. November. Now you've also testified at some trials; correct?
12 13 14 15 16 17 18 19 20 21	just show you this we're not going to mark it at this point but it was a longer list like this, right? A. Yes. That looks more familiar than this. Q. Okay. And so you brought the billing that pertained to those women's cases, right? A. Um-hum. Q. Okay. A. Yes.	12 13 14 15 16 17 18 19 20 21	depositions. So you gave a deposition in April or in that timeframe for Ethicon, have you given depositions in any cases involving any other manufacturers of transvaginal mesh? A. Yes. Q. Okay. Which others? A. Bard. Q. When was that deposition? A. Let me turn it up. The deposition for Bard was in November. Q. November. Now you've also

Page 14 Page 16 tissue and mesh samples, observed any differences 1 and when were they? 1 2 A. Both were for Boston Scientific 2 that you believe would increase or decrease the 3 devices. One trial was in August for Ms. Cardenas 3 risk of clinical complications in women, depending and the other one was in Miami for Ms. Eghanayem on the type of mesh that is used? 4 4 5 5 MR. ORENT: Objection. and other patients. THE WITNESS: Define "type." Different 6 6 Q. Going back to depositions, you 7 also had -- besides the time that I took your 7 manufacturer, different device, different knit 8 deposition in January with Ms. Weiler for Boston 8 pattern? I mean, what, what exactly --9 Scientific, you also had a deposition in July, 9 BY MS. BYARD: 10 where you covered, specifically, the Cardenas and 10 Q. Any of those are fine. It's an the Eghanayem matters, right? 11 open-ended question. 11 12 12 A. In some lightweighter meshes, A. That's correct. 13 there is more inclusion of normal tissue into the 13 Q. So all told, you've been deposed 14 pores. The difference is not drastic, but there 14 once in the Boston Scientific MDL; once for two 15 15 is -- at the same time, these lightweight meshes specific cases in the Boston Scientific MDL; once for Ethicon --16 fold easier, so it defeats the purpose of the 16 17 design. 17 A. Twice. 18 But theoretically, they're flat. They 18 Q. Twice for Ethicon. Then a 19 would behave better than those more heavier with 19 deposition for Bard? 20 less pores. I mean, there are drawbacks and cons 20 A. Twice for Bard. 21 and pros of this, but the design behaves slightly 21 O. Twice for Bard. And so we're in 22 differently than other designs -- than heavier 22 the neighborhood of six or seven depositions? 23 weight designs. That's what I can say. 23 A. That's correct. 24 Q. So at this point, based on your 24 Q. And two trials? 25 observations to date, you're not in a position to 25 A. That's correct. Page 15 Page 17 Q. Because we've already covered so 1 1 say that those designs are safer or would minimize 2 the risk of clinical complications in women, right? 2 many of your opinions with you in these other 3 depositions and at trials, I'm not going to rehash 3 MR. ORENT: Objection. 4 a bunch of old ground with you. 4 THE WITNESS: Not to a noticeable degree. 5 I'd like to specifically cover with you 5 BY MS. BYARD: 6 today, your deposition for these wave cases, this 6 Q. Okay. 7 7 A. To detectable degree. general report that you've authored. It's roughly 8 the 93-page report that was submitted in the wave 8 I see they behave differently, the 9 tissue reacts differently. But all of them came to 9 cases, all right? 10 And then I'd also like to cover with 10 me because of complications. you some of the updates to your opinions, if any, 11 11 Q. Right. 12 12 okay, sir? A. So I ended up with specimens which 13 13 are excised complications. Therefore, A. (Witness nods.) complications occurred in those. 14 Q. Has your opinion across these 14 15 depositions and trials been basically the same? 15 Q. And I believe you noted in one of 16 And by that I mean, that the tissue response that 16 your original reports, that there's mesh that has 17 you see the polypropylene mesh is essentially 17 tangs and mesh that doesn't have tangs, comparing 18 Boston Scientific mesh either between products or 18 similar across all the various manufacturers? MR. ORENT: Objection. 19 19 Boston Scientific mesh to other products; do you 20 20 THE WITNESS: Yes, to a degree. I recall that distinction? 21 21 learn a little bit more after examining more A. Yes, there is distinction. I 22 specimens, more details. But basic principles 22 mean, some are tanged; heat treated them in slings, 23 remain the same. 23 but they're not treated along all lengths. Some 24 24 are shorter segment. BY MS. BYARD: 25 25 Q. Have you in your observations of So it also behaves somewhat differently.

Page 18 Page 20 But the end result was they became excised, they 1 1 after excision, or during in vivo? Q. Sure. So you're talking about the 2 were problematic. 2 3 Q. So similarly, you're not in a 3 shape after excision; correct? 4 position today, based on your observations to date, 4 A. That's correct. 5 to testify that the tissue response to the 5 Q. Okay. And when you look at the 6 de-tanged mesh versus tanged mesh, is better or 6 shape after excision, you're not able to say with 7 worse in terms of its likelihood of causing 7 certainty, what the shape of the mesh was in vivo, typically, unless it's completely encased in scar 8 8 complications in women, right? 9 MR. ORENT: Objection. 9 tissue, right? 10 THE WITNESS: That is difficult 10 MR. ORENT: Objection. 11 question. I mean, you're asking likelihood. This 11 THE WITNESS: That's not correct would be more of a clinical question, and to be a 12 statement. I can find features which will give me 12 13 13 clinical trial, larger trial. indication what was shape in vivo. I am able to 14 I can tell you that there is a 14 say what was shape in vivo. 15 different tissue reaction. And I can tell you that 15 BY MS. BYARD: 16 my specimens came to me because patients 16 Q. Let's take that up in a little experienced complications. 17 bit, if you don't mind. 17 18 But I would not be able to give you a 18 Returning, though, to your statement that the heat-treated edges don't curl, was that 19 statement of what's the percentage of improvement 19 your basic observation? 20 or, or lack of improvement. 20 21 BY MS. BYARD: 21 A. Generally, yes. 22 Q. And you wouldn't be able to say 22 Q. Okay. And so the de-tanged 23 that to a reasonable degree of certainty, right? 23 sub-urethral portion of the Boston Scientific mesh MR. ORENT: Objection. slings had a lesser propensity to curl? 24 24 THE WITNESS: I just wouldn't be able 25 A. That's correct. 25 Page 19 Page 21 1 to say that. And these factors, the efficacy, it 1 MR. ORENT: Objection. was a clinical question that had to be a long-term 2 2 BY MS. BYARD: 3 clinical study. 3 Q. In terms of the tissue response, 4 BY MS. BYARD: 4 the amount of inflammation that you've seen was the 5 5 Q. Okay. What were the -- you said same between de-tanged and non-de-tanged mesh, 6 there are some differences. What were the tissue 6 though? 7 7 A. It's exactly the same. There is responses that you've seen that are different 8 between tanged and de-tanged mesh? 8 no difference. No detectable difference. 9 9 A. If it's tanged, the edges don't Q. And you make a distinction between 10 curl as much. So if it's a sling, I can see 10 an inflammatory response that you see under a 11 clearer difference. When it gets excised, the microscope and a foreign body reaction; correct? 11 12 A. A foreign body reaction is an 12 heat-treated portion doesn't curl. But then there 13 is a sharp transition into non-heat-treated 13 inflammatory response. I don't make a distinction. 14 portions, and they curl. 14 O. Okay. 15 A. I make distinction between types 15 So if those slings were not -- I mean, 16 original slings were not heat-treated, so the whole 16 of inflammatory reaction. 17 length is curled into a rope. But if there is 17 Q. In particular, whether or not 18 there is a presence of multinucleated cells or 18 section is treated, that section doesn't curl, but 19 19 giant cells? the ends curl. So I can see the difference. But 20 20 A. These are just microfibers who the design failed in one way or another. 21 21 decided to become multinucleated. So there is no Q. And so a distinction I might try 22 and make throughout the day, and I want to make 22 difference between multinucleated microphage and 23 sure it's accurate. You're talking about the shape 23 single nucleated microphage. Functionally, 24 of the mesh itself, right, if it curls --24 genetically, they're all the same. 25 A. Shape before insertion, or shape 25 Q. Does it tell you whether or not

the inflammatory reaction is in response to a fureign body, lough, depending on the type of macrophage? A. No. All macrophage is a reaction to foreign body. A. No. All macrophage is a reaction to foreign body. A. If there is a foreign body, and there are macrophages, they're reacting. Because, generally, the foreign body or granulomatous reaction is defined as epitheliodi histocytes or macrophages, they're reacting. Because, generally, the foreign body or granulomatous reaction is defined as epitheliodi histocytes or macrophages. D. So if my question were whether you had seen any difference in the foreign body answer would be the same; wouldn't if' No. you didn't see a difference in the foreign body answer would be the same; wouldn't if' No. you didn't see a difference. MR. ORENT: Objection. Asked and answered. HIE WITNESS: That's correct. I did not see the difference. D. O. Kay. I want to look at your billing records once we have copies of them, but do you have a number in mind of all told how much your we have a number in mind of all told how much you've been paid by Plaintiffs in the mesh Page 23 I bitigation for your expert work against Boston S. List hard to say now, because 1 don't keep that exact records, really, I'm so busy. Last year my income tax return was 6. S.24.000 from depositions and statements. This year it's larger. I don't know how much larger. MR. ORENT: Objection. THE WITNESS: Possibly. MR. ORENT: Objection. THE WITNESS: I don't want to guess. MY MS. BYARD: Q. Could it be three times larger? MR. ORENT: Objection. THE WITNESS: I don't want to guess. MR. ORENT: Objection. MR. ORENT: Objection. THE WITNESS: I would have to - MR. ORENT: Objection. MR. ORENT: Objection. MR. ORENT: Objection. THE WITNESS: I would have to - MR. ORENT: Objection. MR. ORENT: Objection. THE WITNESS: I would have to - MR. ORENT: Objection. MR. ORENT: Objection. THE WITNESS: I would have to - MR. ORENT: Objection. MR. ORENT: Objection. THE WITNESS: I would have to - MR. ORENT: Objection		Page 22		Page 24
macrophage? A No. All macrophage is a reaction to foreign body. O, Okay. A If there is a foreign body, and there are macrophages, they've reacting. Because, generally, the foreign body or granulomatous reaction is defined as epithelioid histiocytes or macrophages. O, So if my question were whether you had seen any difference in the foreign body reaction between de-tanged and tanged meshes, your reaction between de-tanged and tanged meshes, your answer would be the same; wouldn't it? No, you didn't see a difference? TMR, ORINT: Objection. Asked and answered. THE WITNESS: That's correct. I did not see the difference. DA O, Okay, A Next spring. A Next spring. A Next spring. A Poble you do do anything to prepare for your deposition troday? A I prepared documents for you on the same; wouldn't it? No, you didn't see a difference? A Yes, we met yesterday. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposition here today? A No. D Have you prepared by phone for your deposit	1	the inflammatory reaction is in response to a	1	complete the billing.
4 No. All macrophage is a reaction 5 to foreign body. 6 Q. Okay. 7 A. If there is a foreign body, and 8 there are macrophages, they're reaction. Because, 9 generally, the foreign body or granulomatous 10 reaction is defined as epithelioid histocytes or 11 macrophages. 12 Q. So if my question were whether you 13 had seen any difference in the foreign body 14 reaction between de-tanged and tanged meshes, your 15 answer would be the same; wouldn't it? No, you 16 didn't see a difference? 17 MR. ORENT: Objection. Asked and 18 answered. 19 THE WITNESS: Thar's correct. I did 19 THE WITNESS: Thar's correct. I did 19 THE WITNESS: Thar's correct. I did 20 not see the difference. 21 By Ms. ByARD: 22 Q. Okay. I want to look at your 23 billing records once we have copies of them, but do 24 you have a number in mind of all lold how much 25 you've been paid by Plaintiffs in the mesh 26 S24,000 from depositions and statements. This year 16 litigation for your expert work against Boston 28 Scientific? 3 A. It's hard to say now, because I 4 don't keep that exact records, really, I'm so busy. 29 Last year my income tax return was 5 S24,000 from depositions and statements. This year 16 litigation for your expert work against Boston 29 Scientific? 3 A. It's hard to say now, because I 4 don't keep that exact records, really, I'm so busy. 4 Last year my income tax return was 5 S24,000 from depositions and statements. This year 16 litigation for your expert work against Boston 29 Q. So you hadn't worked on mesh 29 MR. ORENT: Objection. 20 Lit would have to complete of the three times larger? 3 MR. ORENT: Objection. 4 THE WITNESS: I don't want to guess. 5 By Ms. By ARD: 10 THE WITNESS: I don't want to guess. 11 By Ms. By Arg. 12 Q. Okad thave to complete of the manufacturers? 13 MR. ORENT: Objection. Form. 14 THE WITNESS: I would have to complete 15 billing, which I have not completed yet. I mean, 25 billing which I have not completed yet. I mean, 26 calculate for me how much money you've been paid by plaintiffs for acting as an expert	2	foreign body, though, depending on the type of	2	BY MS. BYARD:
5 to foreign body. 6 Q. Okay. 7 A. If there is a foreign body, and 8 there are macroplages, they're reacting. Because, 9 generally, the foreign body or granulomatous 10 reaction is defined as epithelioid histiocytes or 11 macrophages. 12 Q. So if my question were whether you 13 had seen any difference in the foreign body 14 reaction between de-tanged and tanged meshes, your 15 answer would be the same; wouldn't it? No, you 16 didn't see a difference? 17 MR. ORENT: Objection. 18 answered. 19 THE WITNESS: That's correct. I did 19 THE WITNESS: That's correct. I did 20 not see the difference. 21 BY MS. BY ARD: 22 Q. Okay. I want to look at your 23 billing records once we have copies of them, but do you have a number in mind of all told how much 25 you've been paid by Plaintiffs in the mesh Page 23 1 hitgation for your expert work against Boston 2 Scientifie? 3 A. It's hard to say now, because I 4 don't keep that exact records, really, I'm so busy. 2 Last year my income tax return was 5 S24,000 from depositions and statements. This year 16 size are my income tax return was 6 S24,000 from depositions and statements. This year 17 it's larger. I don't know how much larger. 18 Q. Is it two times larger? 29 MR. ORENT: Objection. 20 Q. What would you need to do to calculate for me how much money you've been paid by plaintiffs for acting as an expert against mesh 20 A. I would have to - 21 MR. ORENT: Objection. Form. 22 THE WITNESS: I don't want to guess. 23 billing, which have not completed yet. I mean, 24 this is a long list, it kleas a long time to 25 MR. ORENT: Objection. Form. 26 THE WITNESS: I would have to complete 27 that was an original mesh as opposed to hernia mesh; correct? 28 billing, which have not completed yet. I mean, 29 the wind and the proper refor 29 don't requestion today? 29 A. A couple objection. 29 G. No, we make the proper of the p	3	macrophage?	3	Q. But you will by the time you file
6 Q. And when do you anticipate doing 7 A. If there is a foreign body, and 8 there are macrophages, they're reacting. Because, 9 generally, the foreign body or granulomatous 10 reaction is defined as epithelioid histiocytes or 11 macrophages. 12 Q. So if my question were whether you 13 had seen any difference in the foreign body 14 reaction between de-tanged and tanged meshes, your 15 answer would be the same; wouldn't it? No, you 16 didn't see a difference? 17 MR. ORENT: Objection. Asked and 18 answered. 19 THE WITNESS: That's correct. I did 19 A. Yes, we met yesterday. 10 A. Yes, we met yesterday? 11 A. Yes, we met yesterday. 12 Q. Did you meet with counsel to 13 reaction between de-tanged and tanged meshes, your 14 answer would be the same; wouldn't it? No, you 15 didn't see a difference? 16 MR. ORENT: Objection. Asked and 17 A. Yes, we met yesterday. 18 A. No. 19 THE WITNESS: That's correct. I did 19 Q. How long did you meet yesterday? 18 A. No. 20 How long did you meet yesterday? 21 A. A couple of hours. 22 Q. Okay. I want to look at your 22 billing records once we have copies of them, but do 24 you have a number in mind of all told how much 25 you've been paid by Plaintiffs in the mesh 26 S24,000 from depositions and statements. This year 16 it's larger. I don't know how much larger. 29 A. It's hard to say now, because I 30 Go Is it two times larger? 31 A. If's hard to say now, because I 32 A. If's hard to say now, because I 33 A. If's hard to say now, because I 44 don't keep that exact records, really, I'm so busy. 45 Last year my income tax return was 46 \$24,000 from depositions and statements. This year 16 it's larger. I don't know how much larger. 49 MR. ORENT: Objection. 40 Page 23 41 THE WITNESS: I don't want to guess. 41 THE WITNESS: I don't want to guess. 41 THE WITNESS: I don't want to guess. 42 Oy What would you need to do to 43 Calculate for me how much money you've been paid by 44 plaintiffs for acting as an expert against mesh 45 manufacturers? 46 Oy What would you need to do to 47 calculate	4	A. No. All macrophage is a reaction	4	your taxes?
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24 this is a long list, it takes a long time to 24 THE WITNESS: I don't know who	21			
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	21 22 23 24	THE WITNESS: I would have to complete billing, which I have not completed yet. I mean, this is a long list, it takes a long time to	22 23 24	to hernia mesh; correct? MR. ORENT: Objection. THE WITNESS: I don't know who

1 2	Page 26		Page 28
2	was my first transvaginal specimen. Probably an	1	You recognize it, though?
	attorney, probably Dr. Thomson asked me to look at	2	A. Yes, this is my document.
3	it. Maybe, maybe not. I don't know, I don't	3	Q. And if you flip into the document,
4	remember now.	4	you'll see your signature on it? Hopefully.
5	BY MS. BYARD:	5	MR. ORENT: Page 65.
6	Q. Okay. And originally your rate	6	THE WITNESS: Yes, I do.
7	was \$400, and now it's \$475, right?	7	BY MS. BYARD:
8	A. That's correct.	8	Q. What date did you sign this report?
9	Q. And why did you increase your	9	A. November 10th.
10	rate?	10	Q. When did you start working on it?
11	A. As I said, I published, I'm more	11	A. This is a general report, so
12	experienced. It wouldn't be unfair, because when I	12	essentially, this has been transformed original
13	started I had no experience in litigation cases.	13	report. We discussed in January, so it just was
14	Q. So since beginning work on	14	modified several times, reformatted and new images
15	transvaginal mesh matters in 2013, and now sitting	15	were inserted so
16	here today at the end of 2014, you've now published	16	If you ask me when I started working on
17	articles on the subjects of this litigation; correct?	17	this, it would be probably two thousand and
18	A. No, this is not correct. I didn't	18	early late 2013.
19	publish on the subject of litigation. I published	19	Q. Okay. Have you issued similar
20	on my research, on topics of surgical polypropylene	20	reports, reports in formatting similar to this one
21	meshes.	21	in the other mesh manufacturers' cases?
22	Q. Based on your review of specimens	22	A. Yes. Usually we keep the same
23	provided to you by Plaintiffs' attorneys in	23	format, general report and case-specific reports.
24	litigation?	24	Q. Visually, this report appears
25	MR. ORENT: Objection.	25	different than the report I originally deposed you
	Page 27		Page 29
1	THE WITNESS: Most publications	1	about in January of 2014. Do you agree with me
2	actually are based on hernia meshes, which were	2	about that?
3	coming from just regular patients. I examined more	3	A. Yes. This is more structured.
4	specimens for litigation, but publications are	4	Because I understood that, medically, though
5	mostly based on that.	5	moderate, a little bit difference, so it's not a
6	BY MS. BYARD:	6	guide for my report shouldn't be a guide for a
7	Q. Okay. We can take a look at those	7	clinician. It should be more of a legal document.
8	articles. Before we do, though, let's mark your	8	Q. And I understand that you've
9	report as 1196.	9	continually built on your base knowledge in coming
10	MS. BYARD: Do you need a copy, John?	10	at what we have here as a final work product. But
11	MR. ORENT: Yeah, we'll take copies of	11	when was the transition made between the format of
	everything, just position them on my list here	12	a report that we looked at in January of 2014 to
12			
12 13	somewhere.	13	what we see here today?
	somewhere. EXHIBIT NO. 1196: General Expert	13 14	what we see here today? MR. ORENT: Objection.
13			
13 14	EXHIBIT NO. 1196: General Expert	14	MR. ORENT: Objection.
13 14 15	EXHIBIT NO. 1196: General Expert Report of Dr. Vladimir Iakovlev dated	14 15	MR. ORENT: Objection. THE WITNESS: In October or November.
13 14 15 16	EXHIBIT NO. 1196: General Expert Report of Dr. Vladimir Iakovlev dated November 10, 2014. BY MS. BYARD:	14 15 16	MR. ORENT: Objection. THE WITNESS: In October or November. Because some of the supplied reports, they had older general part, older format. And some had
13 14 15 16 17	EXHIBIT NO. 1196: General Expert Report of Dr. Vladimir Iakovlev dated November 10, 2014. BY MS. BYARD: Q. Doctor, do you recognize 1196?	14 15 16 17	MR. ORENT: Objection. THE WITNESS: In October or November. Because some of the supplied reports, they had older general part, older format. And some hadso it was somewhere in during my work on this
13 14 15 16 17 18	EXHIBIT NO. 1196: General Expert Report of Dr. Vladimir Iakovlev dated November 10, 2014. BY MS. BYARD: Q. Doctor, do you recognize 1196? A. Strange, 1196. Where are 1195?	14 15 16 17 18	MR. ORENT: Objection. THE WITNESS: In October or November. Because some of the supplied reports, they had older general part, older format. And some had so it was somewhere in during my work on this report. I had to streamline it. This is a huge
13 14 15 16 17 18	EXHIBIT NO. 1196: General Expert Report of Dr. Vladimir Iakovlev dated November 10, 2014. BY MS. BYARD: Q. Doctor, do you recognize 1196? A. Strange, 1196. Where are 1195? Q. Sorry, that's just the exhibit	14 15 16 17 18 19	MR. ORENT: Objection. THE WITNESS: In October or November. Because some of the supplied reports, they had older general part, older format. And some had so it was somewhere in during my work on this report. I had to streamline it. This is a huge number, a huge amount of work. I had to streamline
13 14 15 16 17 18 19 20	EXHIBIT NO. 1196: General Expert Report of Dr. Vladimir Iakovlev dated November 10, 2014. BY MS. BYARD: Q. Doctor, do you recognize 1196? A. Strange, 1196. Where are 1195? Q. Sorry, that's just the exhibit number. Do you recognize this document?	14 15 16 17 18 19 20 21	MR. ORENT: Objection. THE WITNESS: In October or November. Because some of the supplied reports, they had older general part, older format. And some had so it was somewhere in during my work on this report. I had to streamline it. This is a huge number, a huge amount of work. I had to streamline it and kind of organize it in a way that it would
13 14 15 16 17 18 19 20 21	EXHIBIT NO. 1196: General Expert Report of Dr. Vladimir Iakovlev dated November 10, 2014. BY MS. BYARD: Q. Doctor, do you recognize 1196? A. Strange, 1196. Where are 1195? Q. Sorry, that's just the exhibit number. Do you recognize this document? A. Yes, I do recognize this. It's	14 15 16 17 18 19 20 21 22	MR. ORENT: Objection. THE WITNESS: In October or November. Because some of the supplied reports, they had older general part, older format. And some had so it was somewhere in during my work on this report. I had to streamline it. This is a huge number, a huge amount of work. I had to streamline it and kind of organize it in a way that it would be easier to produce this large number.
13 14 15 16 17 18 19 20 21 22 23	EXHIBIT NO. 1196: General Expert Report of Dr. Vladimir Iakovlev dated November 10, 2014. BY MS. BYARD: Q. Doctor, do you recognize 1196? A. Strange, 1196. Where are 1195? Q. Sorry, that's just the exhibit number. Do you recognize this document? A. Yes, I do recognize this. It's just, exhibit usually starts with number one, but	14 15 16 17 18 19 20 21 22 23	MR. ORENT: Objection. THE WITNESS: In October or November. Because some of the supplied reports, they had older general part, older format. And some had so it was somewhere in during my work on this report. I had to streamline it. This is a huge number, a huge amount of work. I had to streamline it and kind of organize it in a way that it would be easier to produce this large number. BY MS. BYARD:
13 14 15 16 17 18 19 20 21	EXHIBIT NO. 1196: General Expert Report of Dr. Vladimir Iakovlev dated November 10, 2014. BY MS. BYARD: Q. Doctor, do you recognize 1196? A. Strange, 1196. Where are 1195? Q. Sorry, that's just the exhibit number. Do you recognize this document? A. Yes, I do recognize this. It's	14 15 16 17 18 19 20 21 22	MR. ORENT: Objection. THE WITNESS: In October or November. Because some of the supplied reports, they had older general part, older format. And some had so it was somewhere in during my work on this report. I had to streamline it. This is a huge number, a huge amount of work. I had to streamline it and kind of organize it in a way that it would be easier to produce this large number.

	Page 30		Page 32
1	case-specific reports today, but some of them	1	testing in a laboratory environment."
2	revert to the earlier format that you used, right?	2	Did I read that correctly?
3	A. Yes.	3	A. Yes, that's correct.
4	Q. But the exhibit that we're looking	4	Q. I believe we previously
5	at, 1196, this reflects the most I guess your	5	established, but I wanted to make sure in light of
6	most distilled version of your opinions in this	6	this language, that you haven't reviewed any of
7	litigation; is that fair?	7	Boston Scientific's internal testing?
8	A. I don't know about distilled, but	8	A. No, not specifically Boston
9	it's most updated version, most recent.	9	Scientific.
10	Q. So if we wanted to talk about your	10	Q. Okay. And have you reviewed any
11	current opinions, it would be better for us to work	11	of Boston Scientific's biocompatibility testing?
12	off of 1196 than the version that I deposed you	12	A. No, not internally.
13	about in January of 2014, right?	13	Q. Have you reviewed any of Boston
14	A. Yes, it would be easier.	14	Scientific's animal testing?
15	Q. Okay. Notwithstanding the fact	15	A. As I said, I had no access to
16	that that older version appears inserted in some of	16	specifically internal documents of Boston Scientific.
17	these case-specific reports that we'll talk about	17	Q. Would it interest you, as a
18	tomorrow, right?	18	pathologist, to see what Boston Scientific's animal
19	A. That's correct.	19	testing revealed about the tissue response to its
20	Q. Okay, good. Turning to your	20	products?
21	report, we start off with your qualifications. Are	21	A. Yes, it would be interesting.
22	you with me?	22	Q. Is that anything that you
23	A. Yes, I am.	23	requested from the Plaintiffs' counsel?
24	Q. Have there been and then we	24	MR. ORENT: Objection.
25	have attached as an exhibit to your report, we have	25	THE WITNESS: It didn't occur to me
	Dama 21		Dama 22
_	Page 31		Page 33
1	your CV; true?	1	that you would provide it.
2	A. Yes, I saw it.	2	BY MS. BYARD:
3	Q. I think it's Exhibit A.	3	Q. And similarly, you haven't done a
4	Apart from the publications that I'll	4	review of the literature for clinical studies
5	talk about here in a moment as they come up in the	5	conducted on Boston Scientific's products, right?
6	report, have there been any other updates to your	6	MR. ORENT: Objection.
7	CV or your qualifications?	7	THE WITNESS: Repeat
8	A. Publications, presentations,	8	MR. ORENT: Hold on one second.
9	abstracts, posters, that's main things, nothing	9	Do you mean "randomized control"?
10	else.	10	Because the term "study" has a very specific
11	Q. Okay.	11	meaning in science.
12	A. I'm still working in the same place.	12	MS. BYARD: Counsel, please don't coach
13	Q. Same place, same title?	13	the witness with your objections.
14	A. (Witness nods.)	14	MR. ORENT: No. I'm asking you to
15	Q. Very good. And if we go further	15	clarify the question.
16	into your report, you have a section it's the	16	BY MS. BYARD:
17	second paragraph on page 2. It's the first full	17	Q. Clinical studies, studies in
18	paragraph.	18	humans.
19	Here where you're talking about the	19	What does "clinical studies" mean to
20	research that you started with Dr. Bendavid, you	20	you, sir?
21	mention in the last sentence that:	21	A. Please repeat the first question.
	"Previous studies in	22	Q. Sure. What does clinical what
22			
23	manufacturers' testing have been	23	does the term
	manufacturers' testing have been concentrated on experimental modeling in animals and controlled	23 24 25	does the term A. No, no, previous question. Q. No, that's okay. It's my

3 prior question? 4 MS. BYARD: Yes, I'll withdraw that. 5 BY MS. BYARD: 6 Q. What does the term "clinical 7 studies" mean to you as opposed to "preclinical 8 studies"? 9 A. Clinical studies, when it's 10 experimentational testing is done on patients. 3 now to sort out, maybe 4 Q. Okay. And 5 time you updated this s 6 A. Late Augus 7 somewhere in that time 8 could, could do that. 9 MR. ORENT: 10 your voice up.	d so when was the last
3 prior question? 4 MS. BYARD: Yes, I'll withdraw that. 5 BY MS. BYARD: 6 Q. What does the term "clinical 7 studies" mean to you as opposed to "preclinical 8 studies"? 9 A. Clinical studies, when it's 10 experimentational testing is done on patients. 3 now to sort out, maybe 4 Q. Okay. And 5 time you updated this s 6 A. Late Augus 7 somewhere in that time 8 could, could do that. 9 MR. ORENT: 10 your voice up.	e Christmastime. d so when was the last spreadsheet? st, early September,
4 MS. BYARD: Yes, I'll withdraw that. 5 BY MS. BYARD: 6 Q. What does the term "clinical 7 studies" mean to you as opposed to "preclinical 8 studies"? 9 A. Clinical studies, when it's 10 experimentational testing is done on patients. 4 Q. Okay. And 5 time you updated this s 6 A. Late Augus 7 somewhere in that time 8 could, could do that. 9 MR. ORENT: 10 your voice up.	d so when was the last spreadsheet? st, early September,
5 BY MS. BYARD: 5 time you updated this s 6 Q. What does the term "clinical 6 A. Late Augus 7 studies" mean to you as opposed to "preclinical 7 somewhere in that time 8 studies"? 8 could, could do that. 9 A. Clinical studies, when it's 9 MR. ORENT: 10 experimentational testing is done on patients. 10 your voice up.	spreadsheet? st, early September,
6 Q. What does the term "clinical 6 A. Late Augus 7 studies" mean to you as opposed to "preclinical 7 somewhere in that time 8 studies"? 8 could, could do that. 9 A. Clinical studies, when it's 9 MR. ORENT: 10 experimentational testing is done on patients. 10 your voice up.	st, early September,
7 studies" mean to you as opposed to "preclinical 7 somewhere in that time 8 studies"? 8 could, could do that. 9 A. Clinical studies, when it's 9 MR. ORENT: 10 experimentational testing is done on patients. 10 your voice up.	
8 studies"? 8 could, could do that. 9 A. Clinical studies, when it's 9 MR. ORENT: 10 experimentational testing is done on patients. 10 your voice up.	e. It was slow time, so I
9 A. Clinical studies, when it's 9 MR. ORENT: 10 experimentational testing is done on patients. 10 your voice up.	
10 experimentational testing is done on patients. 10 your voice up.	
	Vladimir, can you just keep
11 71111 1117 1117	
11 Q. Okay. Have you reviewed any of 11 THE WITNESS	S: Sure, yeah. Just remind
the clinical studies, so testing on humans, of 12 me.	
13 Boston Scientific's products? 13 BY MS. BYAR	₹D:
14 MR. ORENT: Objection. 14 Q. I don't know	w that we have a copy
THE WITNESS: I have reviewed published 15 of the spreadsheet, so the spreadsheet, so the spreadsheet is the spreadsheet.	that's something that I
16 literature from clinical studies, including Boston 16 would request.	
17 Scientific. Usually it's a mix, it's not a 17 A. I provided it	it in July. I don't
18 separate sometimes it's a separate device, but 18 remember if I updated	since then, but it could be a
19 mostly it's a mix. 19 small update.	
20 BY MS. BYARD: 20 Q. Okay.	
21 Q. Okay. So you couldn't say, you 21 A. But you rec	ceived a copy in July.
22 couldn't sit here today and testify that you've 22 I think in July it was 97	7 transvaginal cases.
23 reviewed all 25-plus Obtryx studies, for instance; 23 Q. So I don't, t	though, have a
	d reflect this 120 number of
	ere in your report, right?
Page 35	Page 37
1 I think the record speaks to the fact 1 A. I'm not sure	if it exists. And,
	I know the number because
3 MS. BYARD: Counsel, please, make a 3 I could count them quick	
4 form objection. 4 entered in the spreadshe	
· · · · · · · · · · · · · · · · · · ·	ess I should back up
6 filled with publications which I reviewed. I don't 6 for a second.	•
7 remember how many of those were Obtryx and so 7 Are you fully pro	repared to discuss all
8 but I can tell you that I read a lot of clinical 8 the opinions that are set	-
9 studies. 9 today?	
10 BY MS. BYARD: 10 A. Yes.	
11 Q. Okay. I want to turn to the next 11 Q. Okay. And	have you seen
12 paragraph here in this preface to your report, 12 everything that you need	
which talks about your review of polypropylene mesh 13 opinions that are set for	
14 explants. Are you with me? 14 A. Yes.	
	do you have any
16 Q. And you reference, "now having 16 additional info, information of the control of the contr	
	ons that are reflected here
18 explants." 18 in Exhibit 1196?	
1	
19 A. This number is probably higher 19 A. No.	did your roport is also do
1 , 5	ara your report include
20 now, something like 150. 20 Q. Okay. And	
20 now, something like 150. 20 Q. Okay. And 21 Q. Is there a way that you track this 21 all of the opinions, the b	basis and the reasons for
20 now, something like 150. 21 Q. Is there a way that you track this 22 number? 20 Q. Okay. And 21 all of the opinions, the b	
20now, something like 150.20Q. Okay. And21Q. Is there a way that you track this21all of the opinions, the b22number?22your opinions that you i23A. When I have time, I sit and then23these matters?	basis and the reasons for intend to offer in trial on
20 now, something like 150. 21 Q. Is there a way that you track this 22 number? 23 A. When I have time, I sit and then 20 Q. Okay. And 21 all of the opinions, the beginning that you is 22 your opinions that you is 23 these matters?	basis and the reasons for intend to offer in trial on see basis of my opinions

	Page 38		Page 40
1	cannot fit in this report. It's just a summary.	1	BY MS. BYARD:
2	Q. Are all of the opinions that you	2	Q. Okay. I'd like to look with you,
3	intend to offer at trial set forth in this report,	3	and I'll represent to you that these are reports
4	Exhibit 1196?	4	that my expert, Dr. Steven Badylak, put together
5	A. As I said, there's a summary, yes.	5	based on specimens that he reviewed.
6	Q. And you understand that if there	6	And the first is for a woman named
7	are updates to this information, that you'll	7	Ellen Hoffman; another is for a woman named Connie
8	supplement this through counsel, right?	8	Bennett; and another is for a woman named Deborah
9	MR. ORENT: Objection.	9	Kilgore. If you wouldn't mind taking the time to
10	THE WITNESS: That's correct.	10	just briefly review those.
11	BY MS. BYARD:	11	MR. ORENT: Let me see those.
12	Q. Of these 120 samples that of	12	THE WITNESS: They look awfully short
13	transvaginal mesh that you had at least as of the	13	in comparison to mine.
14	date that you authored your report and signed it,	14	MS. BYARD: There was no question
15	how many of those had come to you through	15	pending, sir.
16	Plaintiffs' attorneys?	16	MR. ORENT: I have multiple objections
17	A. Ratio is somewhat close to	17	to the use of these documents by Dr. Iakovlev.
18	70 percent. Again, it's approximate ratio.	18	Particularly, one, to the extent that
19	Q. Previously when we've deposed you,	19	this contains information that may relate to the
20	you've testified that you didn't know how the	20	private healthcare information of individuals who
21	Plaintiffs' attorneys selected the specimens that	21	Dr. Iakovlev has not intended to offer any specific
22	they sent to you; do you recall that?	22	testimonies on.
23	A. I don't know the specific details,	23	So to the extent that this relates to
24	but I think it's an irrelevant question, because	24	any protected healthcare information under HIPAA,
25	nobody knows what's in the specimen unless you look	25	I'm going to place an objection on the record to
	Page 39		Page 41
1	in the microscope. So they selected it blindly.	1	that.
2	MS. BYARD: Object and move to strike.	2	Second, to the extent that it goes
2 3	MS. BYARD: Object and move to strike. BY MS. BYARD:	2 3	Second, to the extent that it goes beyond the scope of any of his opinions, I would
2 3 4	MS. BYARD: Object and move to strike. BY MS. BYARD: Q. Do you recall having testified	2 3 4	Second, to the extent that it goes beyond the scope of any of his opinions, I would object to that.
2 3 4 5	MS. BYARD: Object and move to strike. BY MS. BYARD: Q. Do you recall having testified before that you didn't know how the Plaintiffs'	2 3 4 5	Second, to the extent that it goes beyond the scope of any of his opinions, I would object to that. And, I object to asking him to form new
2 3 4 5 6	MS. BYARD: Object and move to strike. BY MS. BYARD: Q. Do you recall having testified before that you didn't know how the Plaintiffs' attorneys selected the specimens that they sent to	2 3 4 5 6	Second, to the extent that it goes beyond the scope of any of his opinions, I would object to that. And, I object to asking him to form new opinions on the basis of something that he's never
2 3 4 5 6 7	MS. BYARD: Object and move to strike. BY MS. BYARD: Q. Do you recall having testified before that you didn't know how the Plaintiffs' attorneys selected the specimens that they sent to you?	2 3 4 5 6 7	Second, to the extent that it goes beyond the scope of any of his opinions, I would object to that. And, I object to asking him to form new opinions on the basis of something that he's never seen before today.
2 3 4 5 6 7 8	MS. BYARD: Object and move to strike. BY MS. BYARD: Q. Do you recall having testified before that you didn't know how the Plaintiffs' attorneys selected the specimens that they sent to you? MR. ORENT: Wait a minute. Hold on.	2 3 4 5 6 7 8	Second, to the extent that it goes beyond the scope of any of his opinions, I would object to that. And, I object to asking him to form new opinions on the basis of something that he's never seen before today. And third, I'm not sure we have
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1 you reviewed a pathological specimen for Ellen 2 Hoffman? 3 MR. ORENT: And I'm also going to 4 object, because that is - to the extent that 5 you're saking questions whether or not he's been a 6 disclosed or undisclosed expert, he doesn't need to 7 answer that question under Rule 26. 8 So I'm going to instruct you not to 9 answer that question under Rule 26. 9 De BY MS. BYARD: 10 BY MS. BYARD: 11 Q. Are you going to follow Counsel's 12 instruction? 13 A. Yes. 14 Q. Have you reviewed a specimen for 15 Debornak Rigore? 16 MR. ORENT: I need to consult with the 17 witness on this. 18 MS. BYARD: Okay. We can go off the 18 witness on this. 19 record. 20 THE VIDEOGRAPHER: Off the record at 21 9:50 a.m. 22 - RECESS AT 9:50 - 23 - UPON RESUMING AT 9:59 - 24 THE VIDEOGRAPHER: Off the record at 25 We're back on the record at 9:59 a.m. 26 Dr. Iakovlev. 27 A. But - 28 We're back on the record at 9:59 a.m. 29 pinking for the witness on this. 20 THE VIDEOGRAPHER: Off the record at 21 pinking for the witness of the back on the record at 9:59 a.m. 21 pinking for the witness of the witness of the witness on this issue a report on the list. 29 Pinking for the witness of the		Page 42		Page 44
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anything else in those cases, or generally speaking. BY MS. BYARD: Q. Are you going to follow Counsel's 11 BY MS. BYARD: Q. Have you reviewed a specimen for 14 Did you review her pathology specimens? A. Yes. Deborah Kilgore? 15 A. I would have to check. (Witness reviews documents.) MR. ORENT: I need to consult with the witness on this. MS. BYARD: Okay. We can go off the record. THE VIDEOGRAPHER: Off the record at 21 9.50 a.m. 21 Q. Okay. So A. But Q. Vou know you didn't issue a report on Ellen Hoffman. THE WITNESS: I don't recall. But again, I don't remember now. Page 43 MR. ORENT: So, Counsel, and I have spoken with 3 Dr. Iakovlev. The issue that is concerning Plaintiffs' counsel for the MDL, is that there is the chance that we are moving from areas where Dr. Iakovlev. 3 Individual case counsel in a consulting capacity. 9 individual case counsel in a consulting capacity. 12 Individual case counsel in a consulting capacity. 13 Individual case counsel in a consulting capacity. 14 Individual case counsel in a consulting capacity. 15 Individual case counsel in a consulting capacity. 16 Individual case counsel in a consulting capacity. 17 Individual case counsel in a consulting capacity. 18 Individual case counsel in a consulting capacity. 19 Individual case counsel in terms of the capacity of the factual nature of things that he saw, or didn't see. 19 Individual case counsel in terms of the capacity of the factual nature of things that he saw, or didn't see. 19 Individual case	7	answer that question under Rule 26.	7	particular samples, we're not waiving anything in
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	Page 46		Page 48
1	instruct the witness not to answer.	1	A. Ask the question again.
2	BY MS. BYARD:	2	Q. You'll acknowledge, though, won't
3	Q. Do you know if there are instances	3	you, that women have excisions following pelvic
4	when counsel had pathological specimens that were	4	surgery, resulting in specimens that don't even
5	never provided to you?	5	contain mesh?
6	A. How would I know that?	6	A. Yes. There are some specimens
7	Q. And returning to Deborah Kilgore,	7	which don't contain mesh.
8	did you review pathology for her?	8	Q. Those were surgeries performed
9	MR. ORENT: Again, subject to my prior	9	because women were experiencing complications,
10	objections.	10	right?
11	THE WITNESS: She's not on the list.	11	MR. ORENT: Objection.
12	BY MS. BYARD:	12	THE WITNESS: Specimens I received
13	Q. And the list that you're referring	13	don't have mesh. But I don't know if they had mesh
14	to, is a list of cases where you have reports that	14	while they were processed in the original
15	have been noticed for the deposition, right?	15	institution.
16	A. Yes. And there are a few more,	16	So what happens, original institution
17	which are not on the list. But I may not recall	17	shaves off subtissue, puts it in the block, and the
18	it. I mean, there is a huge number, like there is	18	mesh is discarded.
19	30. How can I remember all these names?	19	So if it was original excised, and I
20	Q. Okay. You're not looking at a	20	didn't receive it, or it wasn't excised, this, this
21	chain of custody for specimens that have been	21	sometimes is a difficult question.
22	received by your lab, from Steelgate, are you?	22	BY MS. BYARD:
23	A. No, we're not looking at that. I	23	Q. And you don't even know if the
24	could have received some sometimes specimens	24	original institution shaved off the tissue or
25	come dry, and I cannot examine it. Or there is a	25	whether there was even mesh to begin with; correct?
	Page 47		Page 49
1	piece of suture or calcification, something like	1	A. In some cases it's described in
2	this. I mean	2	the pathology report, that they describe mesh; but
3	Q. Okay.	3	they didn't submit sections.
4	A. Or in some cases, it's not mesh,	4	Q. And in other
5	it's like a uterus or	5	A. If I have a pathology report.
6	I think even for uterus, I issued a	6	Sometimes I don't have a pathology report.
7	report but	7	Q. Now, they use 120 samples that you
8	Q. So in some of the pathological	8	speak of in your report. Do those include
9	specimens that you've received, there isn't even	9	specimens that you received where you never
10	any mesh, right?	10	ultimately issued a report?
11	A. In some specimen, yeah, I receive	11	A. Which report? That's a question,
12	sometimes just a it's mucosa, or scar tissue	12	surgical pathology report, report which is served?
13	with some changes adjacent to the mesh, sometimes	13	Q. Either one.
14	just mucosa.	14	A. No. I enter only those cases I
15	Q. In those instances, you don't	15	examine in one way or another and actually,
16	issue a report, do you?	16	those 120 samples, they had mesh. So I could find
17	MR. ORENT: Objection.	17	features specific for the mesh. Either mesh or
18	THE WITNESS: It depends. If I see	18	features specific for the mesh.
19	MR. ORENT: I'm going to instruct the	19	Q. So these 120 exclude cases where
20	witness not to answer this particular question.	20	there were no findings related to mesh?
20		21	A. No.
21	BY MS. BYARD:		
21		22	MR. ORENT: Objection.
	Q. You'll acknowledge, though, won't		MR. ORENT: Objection. BY MS. BY ARD:
21 22	Q. You'll acknowledge, though, won't you, that women have excisions following pelvic	22	BY MS. BYARD:
21 22 23	Q. You'll acknowledge, though, won't	22 23	

Page 50 Page 52 1 So the specimen contains a mesh, and 1 Assuming if I receive three, four 2 it's from vaginal area, then I examine it. If it's 2 specimens for the same patient, I get three, four 3 specimen -- sometimes, as I said, I receive a 3 different surgical pathology cases. Or, if two 4 4 uterus. So why would I include the uterus -specimens were excised on the same day, they can be 5 5 findings of a uterus in a spreadsheet which is accessioned as one surgical number with A and B. It 6 6 research -- which is made for research purposes for depends on the patient. Sometimes it's 1 and 2, 7 7 mesh. A and B. 8 So I examined those, I issue report for 8 So, are you counting number of cases, 9 uterus, but then they don't use it for this 9 or are you counting number of patients, or are you 10 10 purpose, research purpose. So it's not listed counting number of meshes? Some patients have 11 11 there. Or sometimes I receive three, four three meshes. 12 12 specimens for the same patient. Some of them have Q. How do you log it? 13 13 sort of piecemeal excision at the same time, or A. We log by surgical number in 14 14 St. Michael's Hospital. So if a specimen comes as excisions are spread during time. 15 a one, on one single requisition, marked A and B, Q. So for any specimen that you 15 16 receive, provided there is mesh, you issue a 16 it becomes one surgical number. Specimen A and 17 specimen B. But sometimes I receive them spread in 17 pathology report? 18 A. Sooner or later, I -- any specimen 18 time, and then the accessioning becomes spread in 19 which came in and had to be registered at 19 time, so there are two surgical numbers. 20 St. Michael's Hospital, I issue surgical pathology 20 Or, if I can catch it, when I receive 21 21 report. it, then I can put it on the same number, just add 22 Q. And does that include the 22 it. Again, it's not straightforward sometimes. specimens that you receive through Plaintiff's 23 23 Q. Okay. We don't have in your 24 24 report the number of specimens that you've received counsel? A. Yes. It doesn't matter if it 25 25 by surgical number, do we? Page 51 Page 53 1 contains a mesh or doesn't contain a mesh, surgical 1 MR. ORENT: Objection. 2 2 THE WITNESS: No. I haven't logged pathology report needs to be issued. I have to 3 sign it out as a diagnostic pathologist, and have 3 them, those. 4 to produce surgical pathology report. 4 BY MS. BYARD: 5 Q. So irrespective of whether counsel 5 Q. St. Michael's did, though, didn't 6 6 ultimately disclosed a report for you in a case, they? 7 7 you would have logged it when that specimen came in A. I mean, well, they don't count 8 to you at St. Michael's; true? 8 number of specimens received. I can try to do 9 MR. ORENT: Objection. 9 search by words, like "vaginal mesh" or something 10 THE WITNESS: That's true. I cannot do 10 like this. But sometimes they come without staining or I cannot do anything without logging it in. 11 11 definition of mesh, so accessioning clerk doesn't 12 12 BY MS. BYARD: know that it's mesh, and it's just entered as 13 Q. Okay. And so the 120 number would 13 "tissue." So this would escape search by word. 14 be your number of what -- the number of specimens 14 Q. So today, there's no way for us to that you had received? 15 15 recreate however many specimens you've received 16 A. 120 --16 through the mesh litigation? 17 MR. ORENT: Objection. 17 A. Exact up to single specimen? No, THE WITNESS: 120 is mesh specimens. 18 18 this would be difficult. 19 Those specimens I extracted knowledge about mesh 19 There is no -- I mean, in ballpark, 20 body interactions. 120 is not a log number. 20 yes. But, I mean, specifically trace each single 21 21 specimen would be hard. Probably chain of custody BY MS. BYARD: 22 Q. Do you have a log number? 22 forms, this would be easier. But then they are 23 A. It's in St. Michael's information 23 spread all over, I mean, from different sources. 24 system. And cases are accessioned and they are 24 Q. Do you have copies of all the 25 25 chain of custody forms that you've received, the there.

	Page 54		Page 56
1	specimens you've received through the mesh	1	BY MS. BYARD:
2	litigation?	2	Q. In short, you can't assure to me
3	A. Yes, I do keep copies. But	3	that all of the specimens that are available
4	sometimes chain of custody forms comes in, and then	4	through counsel, had been provided to you, can you?
5	there are three specimens behind it. They put on	5	A. How can I? I mean, I ask for
6	one chain of custody forms, and then next patient	6	everything available. Every time there is a new
7	has three different specimens, which are coming	7	specimens, or a new set of specimens coming out,
8	from three different sources with three different	8	I'm asking for all available medical records and
9	chains of custody.	9	all available specimens.
10	And sometimes chain of custody doesn't	10	Q. Beyond that, you can't assure,
11	specify how many specimens, which shape they came	11	though, that your request has been fulfilled?
12	in. I describe them in surgical pathology report	12	MR. ORENT: Objection.
13	each time I describe the specimen.	13	BY MS. BYARD:
14	Q. Okay. So returning to specimens	14	Q. Can you?
15	where you either haven't reviewed or haven't issued	15	A. No.
16	a report that we know of, this Connie Bennett case	16	Q. Similarly, you can't assure me
17	that I mentioned before; is that one that's	17	that every specimen that you've examined has
18	familiar to you?	18	resulted in a report that's been provided to me,
19	MR. ORENT: Subject to my same	19	can you?
20	objections.	20	MR. ORENT: I'm instructing you not to
21	THE WITNESS: As I said, it's not a	21	answer.
22	memory test. I cannot remember.	22	BY MS. BYARD:
23	I don't remember the name. I may or	23	Q. Okay. Let's continue with this
24	may not have is it on the list?	24	paragraph that we're looking at, if you don't mind,
25		25	Doctor. It says:
20		23	Doctor. It says.
	Page 55	23	Page 57
1	Page 55 BY MS. BYARD:	1	Page 57
	BY MS. BYARD:		·
1		1	Page 57 "My data pool of mesh explant samples contains specimens of
1 2	BY MS. BYARD: Q. And again, you're looking at the	1 2	Page 57
1 2 3	BY MS. BYARD: Q. And again, you're looking at the list of your reports?	1 2 3	Page 57 "My data pool of mesh explant samples contains specimens of St. Michael's Hospital patients,
1 2 3 4	BY MS. BYARD: Q. And again, you're looking at the list of your reports? A. Yes. What was the last name?	1 2 3 4	Page 57 "My data pool of mesh explant samples contains specimens of St. Michael's Hospital patients, cases sent from outside hospitals,
1 2 3 4 5	BY MS. BYARD: Q. And again, you're looking at the list of your reports? A. Yes. What was the last name? Q. Connie Bennett, B-E-N-N-E-T-T?	1 2 3 4 5	Page 57 "My data pool of mesh explant samples contains specimens of St. Michael's Hospital patients, cases sent from outside hospitals, as well as potential and active
1 2 3 4 5 6	BY MS. BYARD: Q. And again, you're looking at the list of your reports? A. Yes. What was the last name? Q. Connie Bennett, B-E-N-N-E-T-T? A. (Witness reviews document.) It's not on this list. I could have	1 2 3 4 5	Page 57 "My data pool of mesh explant samples contains specimens of St. Michael's Hospital patients, cases sent from outside hospitals, as well as potential and active litigation cases sent to me as consultant."
1 2 3 4 5 6 7	BY MS. BYARD: Q. And again, you're looking at the list of your reports? A. Yes. What was the last name? Q. Connie Bennett, B-E-N-N-E-T-T? A. (Witness reviews document.)	1 2 3 4 5 6	Page 57 "My data pool of mesh explant samples contains specimens of St. Michael's Hospital patients, cases sent from outside hospitals, as well as potential and active litigation cases sent to me as
1 2 3 4 5 6 7 8	BY MS. BYARD: Q. And again, you're looking at the list of your reports? A. Yes. What was the last name? Q. Connie Bennett, B-E-N-N-E-T-T? A. (Witness reviews document.) It's not on this list. I could have issued the report, could have. I don't remember	1 2 3 4 5 6 7 8	"My data pool of mesh explant samples contains specimens of St. Michael's Hospital patients, cases sent from outside hospitals, as well as potential and active litigation cases sent to me as consultant." My only question here is on percentages.
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	Page 58		Page 60
1	A. I mean, 70 from litigation and 30,	1	of mesh, or more of a raw mesh.
2	about 30 non-litigation.	2	(Reporter sought clarification.)
3	Q. So 30 either from St. Michael's or	3	A. Raw material, raw material of the
4	from outside hospitals?	4	mesh. It's not formal device.
5	A. It's mainly St. Michael's. For	5	Q. Is the Prefyx a sling, or is it
6	transvaginal, it's mainly St. Michael's Hospital.	6	indicated for the treatment of pelvic organ
7	Q. For the outside hospitals, do you	7	prolapse?
8	know how they select which samples they give to you	8	A. Prefyx, I'm not sure about this
9	and which they don't?	9	one.
10	A. Those clinicians, they just send	10	Q. How about the Advantage Fit?
11	whatever is available, consecutive.	11	A. Advantage is I would have to
12	(Reporter sought clarification.)	12	check. I mean, it's not a memory test. Every time
13	A. Consecutive.	13	I see some name I'm not sure, I just Google and
14	Q. But if there are samples that they	14	check with Boston Scientific website.
15	don't send to you, you wouldn't know about that one	15	Q. Sitting here today, though, you
16	way or the other, would you?	16	can't tell me?
17	A. No.	17	MR. ORENT: Objection.
18	MR. ORENT: Objection.	18	THE WITNESS: I wouldn't guess. I
19	BY MS. BYARD:	19	don't want to guess.
20	Q. Okay. Turning to the next page,	20	BY MS. BYARD:
21	the first full paragraph.	21	Q. What about Uphold? Is that
22	And I'm on page 3 of 1196 for the	22	indicated for stress urinary incontinence or for
23	record?	23	pelvic organ prolapse?
24	A. Yes.	24	A. Pelvic organ prolapse.
25	Q. You talk about how pathologists	25	Q. How many incisions are used to
	(,
	Page 59		Page 61
			rage of
1	are trained and develop skills for subjective	1	place a Solyx?
1 2		1 2	
	are trained and develop skills for subjective		place a Solyx?
2	are trained and develop skills for subjective assessments?	2	place a Solyx? A. It's a clinical question. I'm not
2	are trained and develop skills for subjective assessments? A. That's correct.	2 3	place a Solyx? A. It's a clinical question. I'm not a clinician.
2 3 4	are trained and develop skills for subjective assessments? A. That's correct. Q. You write that: "To understand the related pathological processes and make a	2 3 4	place a Solyx? A. It's a clinical question. I'm not a clinician. Q. Where is the incision or incisions
2 3 4 5	are trained and develop skills for subjective assessments? A. That's correct. Q. You write that: "To understand the related	2 3 4 5	place a Solyx? A. It's a clinical question. I'm not a clinician. Q. Where is the incision or incisions located?
2 3 4 5 6	are trained and develop skills for subjective assessments? A. That's correct. Q. You write that: "To understand the related pathological processes and make a	2 3 4 5 6	place a Solyx? A. It's a clinical question. I'm not a clinician. Q. Where is the incision or incisions located? MR. ORENT: Objection.
2 3 4 5 6 7	are trained and develop skills for subjective assessments? A. That's correct. Q. You write that: "To understand the related pathological processes and make a correct diagnosis, pathologists need to understand the function of the devices being analyzed"	2 3 4 5 6 7	place a Solyx? A. It's a clinical question. I'm not a clinician. Q. Where is the incision or incisions located? MR. ORENT: Objection. THE WITNESS: For which type? BY MS. BYARD: Q. Solyx.
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2 3 4 5 6 7 8 9 10	are trained and develop skills for subjective assessments? A. That's correct. Q. You write that: "To understand the related pathological processes and make a correct diagnosis, pathologists need to understand the function of the devices being analyzed" A. That's correct. Q. " their physical characteristics"	2 3 4 5 6 7 8 9 10	place a Solyx? A. It's a clinical question. I'm not a clinician. Q. Where is the incision or incisions located? MR. ORENT: Objection. THE WITNESS: For which type? BY MS. BYARD: Q. Solyx. A. So my understanding is for slings, there is a midline incision, and then there are
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16 (Pages 58 to 61)

	Page 62		Page 64
1	A. Which go through skin, so there	1	Q. So it's your testimony that the
2	you need to make an incision in the skin. But then	2	treatment modalities wouldn't differ depending on
3	it's not an incision linear.	3	whether a pudendal nerve branch versus another
4	Q. Where does the what you're	4	nerve branch were ingrown in mesh?
5	calling the trocar track, or the trocar pass,	5	A. No.
6	compare in location for an Obtryx versus retropubic	6	MR. ORENT: Objection.
7	sling, for instance?	7	BY MS. BYARD:
8	MR. ORENT: Objection.	8	Q. The reality is that you don't
9	THE WITNESS: A retropubic sling	9	treat clinical complications from pelvic mesh, do
10	doesn't go into a transobturator. So the arms go	10	you?
11	retropubically, pointing upward. So it's	11	MR. ORENT: Objection.
12	BY MS. BYARD:	12	THE WITNESS: No.
13	Q. Where do the incisions for the	13	BY MS. BYARD:
14	trocar tracks let me start over.	14	Q. And so you don't need to
15	How do the incisions for the trocar	15	understand, as a pathologist, from your
16	tracks or passes for the Obtryx sling compare to	16	perspective, whether or not the nerve that you see
17	the Advantage sling?	17	is a pudendal nerve, or part of an obturator nerve,
18	MR. ORENT: Objection.	18	or part of the genital femoral nerves, right?
19	THE WITNESS: I think we are going	19	A. I think you're misrepresenting.
20	beyond the scope of what pathologists need to	20	You're talking about large nerves, large branches
21	understand.	21	so which have names. There will be thousands of
22	I need to understand if the sling is	22	other smaller branches, which don't have names.
23	placed in specific anatomical area, and what	23	So you're making it kind of like a
24	anatomical spaces are displaced. Specific details	24	cartoon, more of a reality is different. The
25	of surgical techniques need to be understood only	25	genital area is very richly innervated, nerves
	Page 63		Page 65
1	to a degree, which helps me to understand the	1	coming from different places. You're talking about
2	function.	2	large nerve, but the branches have no names, and
3	So you're asking me very specific	3	then they go in the area. So it's either you have
4	details which would be important for a clinician,	4	a misunderstanding, or just trying to make it look
5			a misunderstanding, or just trying to make it look
	but as a pathologist, they are not as important to	5	like this.
6	me. So, I think we're going beyond what I would	5 6	like this. MS. BYARD: Object and move to strike.
6 7	me. So, I think we're going beyond what I would need to know.		like this. MS. BYARD: Object and move to strike. MR. ORENT: Oppose.
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	Page 66		Page 68
1	A. Specifically, the meshes are not	1	THE WITNESS: I mean, you're asking me
2	stitched to tissues. So they mainly depend on	2	questions which clearly are clinical questions.
3	tissue ingrowth.	3	BY MS. BYARD:
4	Q. How about fixed by placement to	4	Q. Okay.
5	any of the anatomical structures of the pelvis? Do	5	A. As I said, as a pathologist I need
6	you know whether that occurs?	6	to understand what the device looks like, what is
7	MR. ORENT: Objection.	7	it made from, and what anatomical location it is
8	THE WITNESS: What do you mean, "fixed	8	placed, what is its function.
9	by placement"?	9	That's as much that's, basically,
10	Placement is just you place something.	10	generally what I need to know. You're going to
11	BY MS. BYARD:	11	somewhere where it's completely beyond my scope, my
12	Q. What is the Capio?	12	expertise.
13	A. Pardon?	13	Q. You write in your report that you
14	Q. The Capio?	14	need to understand the function of the devices
15	A. I don't know what you're talking about.	15	being analyzed, right?
16	MR. ORENT: Objection. Scope.	16	A. Yes.
17	BY MS. BYARD:	17	Q. You write that you need to know
18	Q. Do Boston Scientific's pelvic mesh	18	the devices' physical characteristics, right?
19	products make use of trocars?	19	MR. ORENT: Objection. These are
20	MR. ORENT: Objection. Vague. Form.	20	THE WITNESS: The functions for stress
21	Scope.	21	urinary incontinence is to support urethra.
22	THE WITNESS: What do you mean?	22	Physical characteristics, I see it's a
23	BY MS. BYARD:	23	polypropylene, it's not biological mesh. That's
24	Q. You used the word "trocars"	24	what I'm talking about.
25	before. What did you mean by that?	25	
	Page 67		Page 69
1	A Tot 1 1 1 1 1 1		
	A. It's a device which comes in the	1	BY MS. BYARD:
2	A. It's a device which comes in the kit. It's more of like a long needle.	1 2	BY MS. BYARD: Q. Okay. But as far as where these
2			
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3	kit. It's more of like a long needle. Q. Do Boston Scientific's pelvic	2 3	Q. Okay. But as far as where these devices pass in the anatomy, based on their
3 4	kit. It's more of like a long needle. Q. Do Boston Scientific's pelvic organ prolapse kits make use of trocars?	2 3 4	Q. Okay. But as far as where these devices pass in the anatomy, based on their surgical placement, you haven't been able to tell
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	Page 70		Page 72
1	and other things. I mean, I receive specimen six	1	edema within mesh compartments, as
2	years later when all incisions are healed.	2	well as innervation with nerve
3	BY MS. BYARD:	3	ingrowth into the mesh compartments,
4	Q. Does the location of the incision	4	vascular abnormalities and mesh
5	help you understand where the device was	5	degradation."
6	anatomically located when it was actually in the	6	Did I read that all reasonably
7	patient's body?	7	correctly?
8	A. It can be very long way from	8	A. That's correct.
9	incision to the placement of the device. So it may	9	Q. How do you define chronic
10	or may not help, but most of the time	10	lymphoplasmacytic
11	For example, if it's a hernia, if it's	11	A. Cytic.
12	open hernia, I know that there was incision from	12	Q cytic inflammation composed of
13	skin. So it's open hernia surgery.	13	foreign body reaction?
14	If it's laparoscopic, I know that the	14	A. Foreign body reaction, as I
15	access was laparoscopically. So it's a different	15	explained before, is a collection of epithelioid
16	anatomical location. So a laparoscopic hernia	16	histiocytes, these are mononucleated or
17	would be more of an intraperitoneal access. That	17	multinucleated. Lymphoplasmacytic, as the word
18	makes a difference.	18	implies, is lymphocytes and plasma cells.
19	If you put sling through incision one	19	Q. How do you define vascular
20	centimeter to the left or right, it will not make a	20	congestion?
21	difference.	21	A. If the vessels are enlarged, then
22	Q. So whether	22	fully packed with red blood cells.
23	A. But it might make a difference for	23	Q. What did you mean by "vascular
24	a surgeon.	24	abnormalities"?
25	Q. So whether or not the sling is	25	A. I see obliterated arteries. I see
	Daga 71		
	Page 71		Page 73
1	placed in the retropubic space as opposed to	1	Page 73 thrombosed capillaries.
1 2		1 2	
	placed in the retropubic space as opposed to		thrombosed capillaries.
2	placed in the retropubic space as opposed to through the transobturator space doesn't make a	2	thrombosed capillaries. Q. And for a lay person, what does
2	placed in the retropubic space as opposed to through the transobturator space doesn't make a difference to you as a pathologist?	2 3	thrombosed capillaries. Q. And for a lay person, what does obliterated arteries and thrombose capillaries
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	placed in the retropubic space as opposed to through the transobturator space doesn't make a difference to you as a pathologist? A. It does make a difference. As I said, this is an anatomical location, that's what I'm I try to understand every time I encounter a new device. But how it was placed specifically, all intricate details of surgical techniques, they're irrelevant for this. Q. Moving to the third paragraph, the third full paragraph on page 3, please, Doctor. A. Yes. Q. You write that you have been able to: "Directly observe changes in the mesh samples, including but not limited to scar encapsulation, scar maturation with contraction, the inflammatory response to the implanted mesh, including but not limited to the foreign body reaction and chronic lymphoplasmacytic inflammation" A. Plasmacytic.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	thrombosed capillaries. Q. And for a lay person, what does obliterated arteries and thrombose capillaries mean? A. A vessel which doesn't supply blood anymore. Q. Are you able to tell, microscopically, when that obliteration occurred? A. To a certain degree. Q. How so? A. Sometimes I can say that it's been week or even month, maybe years, or sometimes it's a relatively recent event, days. Or hours. Q. But how do you discern that microscopically, I think was my question? A. Oh, then I would have to give you a lecture. Vital response, the stages of tissue reacting to a blocked vessel. First, inflammatory cells, then there would be changes in the vascular wall, organization of the thrombus, recolonization. Q. And so when you say you observe an obliterated artery, for instance, would you

	Page 74		Page 76
1	event?	1	Carey and Dr. John Steege, "Pathology of Explanted
2	A. Depends on clinical relevance.	2	Transvaginal Meshes," International Journal of
3	For example, if there is autopsy case	3	Medical Health, Pharmaceutical and Biomedical
4	and I see that the arteries in the heart is	4	Engineering, 2014; is that right?
5	obliterated, it will depend. If it's an old	5	A. Correct.
6	injury, definitely it wasn't cause of death. If	6	Q. The second is an article published
7	it's fresh injury, this can be cause of death.	7	with Dr. Bendavid, Dr. Lou and Koch, "Mesh-Related
8	This is just an example.	8	SIN Syndrome: A Surreptitious, Irreversible
9	Q. And what is thrombosed capillary?	9	Neuralgia and Its Morphologic Background in the
10	What does that term mean for a lay person?	10	Etiology of Post-Herniorrhaphy Pain," International
11	A. Capillaries doesn't supply blood	11	Journal of Clinical Medicine, 2014.
12	anymore.	12	These are both full published articles,
13	Q. Turning to your list of articles	13	right?
14	that you've set forth here, this list, did you	14	A. Yes, these are full articles.
15	intend it to include all of your publications,	15	Q. And then we have a list of
16	abstracts, lectures, oral and poster presentations	16	abstracts. And there's five listed here, right?
17	pertinent to the subject of your report?	17	A. No, there are more. They're all
18	A. Pertinent to my mesh research, yes.	18	included on the flash drive.
19	Q. Okay. All of these are from 2014,	19	Q. There are five listed here, right?
20	right?	20	A. On this page, yes, there are five.
21	A. Yes.	21	Q. How many more are there on that
22	Q. I'd like to	22	thumb drive?
23	A. Just one was earlier. When we	23	A. Maybe a couple. I don't remember now.
24	started	24	Q. And you put this list together
25	Q. Oh, yes. "The Pathological	25	sometime around November 10th, 2014, right?
	Q. C.I., yes. The Lumeregroun		sometime around Provenior Four, 2011, Figure.
	Page 75		Page 77
1			
1	Findings in Explanted Surgical Meshes," that	1	A. October, November, yeah.
2	Findings in Explanted Surgical Meshes," that presentation	1 2	A. October, November, yeah.Q. So the abstracts that are you
2	presentation	2	Q. So the abstracts that are you
2	presentation A. Yes.	2 3	Q. So the abstracts that are you have on your thumb drive, the abstracts that are in
2 3 4	presentation A. Yes. Q that you gave?	2 3 4	Q. So the abstracts that are you have on your thumb drive, the abstracts that are in addition to this list that are available on this
2 3 4 5	presentation A. Yes. Q that you gave? A. The work, as I said, started in 2012.	2 3 4 5	Q. So the abstracts that are you have on your thumb drive, the abstracts that are in addition to this list that are available on this thumb drive, were published since November 10th of
2 3 4 5 6	presentation A. Yes. Q that you gave? A. The work, as I said, started in 2012. Q. For hernia mesh, right?	2 3 4 5 6	Q. So the abstracts that are you have on your thumb drive, the abstracts that are in addition to this list that are available on this thumb drive, were published since November 10th of 2014?
2 3 4 5 6 7	presentation A. Yes. Q that you gave? A. The work, as I said, started in 2012. Q. For hernia mesh, right? A. Yeah. I think I received first	2 3 4 5 6 7	Q. So the abstracts that are you have on your thumb drive, the abstracts that are in addition to this list that are available on this thumb drive, were published since November 10th of 2014? A. Either published or presented. So
2 3 4 5 6 7 8	presentation A. Yes. Q that you gave? A. The work, as I said, started in 2012. Q. For hernia mesh, right? A. Yeah. I think I received first transvaginal mesh very soon, January or February	2 3 4 5 6 7 8	Q. So the abstracts that are you have on your thumb drive, the abstracts that are in addition to this list that are available on this thumb drive, were published since November 10th of 2014? A. Either published or presented. So I usually put something published or presented on
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	Page 78		Page 80
1	Mesh Products: A Biomaterials Perspective Using	1	presentations forms of the articles and abstracts?
2	Materials Science Fundamentals," 2014.	2	A. Not all of them. For the Canadian
3	A. That's correct.	3	hernia meetings, I was just invited to come without
4	Q. Number three is Vladimir Iakovlev:	4	abstracts.
5	"Explanted Surgical Meshes: What Pathologists and	5	Q. Okay. Can you point those out to me?
6	Industry Failed to Do for 50 Years," 2014, right?	6	A. This, number one.
7	A. That's correct.	7	Q. Okay.
8	Q. Yourself, Dr. Guelcher and	8	A. (Witness reviews document.)
9	Dr. Bendavid: "In-vivo Degradation of Surgical	9	This was just an invitation. Number
10	Polypropylene Meshes: A Finding Overlooked for	10	three, also just an invitation. Number five
11	Decades," 2014. Right?	11	Q. Okay.
12	A. That's correct.	12	A this was just an invitation.
13	Q. Number five is an abstract with	13	Yup.
14	yourself, Dr. Erin Teeter Carey, Dr. Iakovleva	14	MR. ORENT: When we get to a good
15	A. Yes.	15	breaking point, we can take our first break.
16	Q Dr. Steege and Dr. Bendavid:	16	MS. BYARD: Now is a fine time for me.
17	"Pathological Findings Associated with Pain in	17	MR. ORENT: Okay.
18	Transvaginal Meshes."	18	THE VIDEOGRAPHER: This marks the
19	A. That's correct.	19	end of media number one, in the deposition of
20	O. 2014.	20	Dr. Vladimir Iakovlev.
21	And then you list here some lectures	21	We're going off the record at 10:43 a.m.
22	and oral presentations.	22	RECESS AT 10:43
23	This first one, is a copy of that	23	EXHIBIT NO. 1197: Article entitled,
24	included in materials that you've provided on the	24	"Mesh-Related SIN Syndrome: A
25	thumb drive?	25	Surreptitious Irreversible Neuralgia
23	ulumo unve:		Surreputations interventione incurating in
	Page 79		Page 81
1	Page 79 A. Yes. I included all what I could	1	Page 81 and Its Morphologic Background in the
1 2	_	1 2	
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2	A. Yes. I included all what I could at this stage, I mean, whatever I had.	2	and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain,"
2 3	A. Yes. I included all what I could at this stage, I mean, whatever I had. Q. Okay. And number two, is that	2 3	and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain," International Journal of Clinical
2 3 4	A. Yes. I included all what I could at this stage, I mean, whatever I had. Q. Okay. And number two, is that essentially a duplication of the fully published	2 3 4	and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain," International Journal of Clinical Medicine, 2014, by Dr. R. Bendavid,
2 3 4 5	A. Yes. I included all what I could at this stage, I mean, whatever I had. Q. Okay. And number two, is that essentially a duplication of the fully published article number one on your list?	2 3 4 5	and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain," International Journal of Clinical Medicine, 2014, by Dr. R. Bendavid, Dr. W. Lou, Dr. A. Koch and Dr. V.
2 3 4 5 6	A. Yes. I included all what I could at this stage, I mean, whatever I had. Q. Okay. And number two, is that essentially a duplication of the fully published article number one on your list? A. Well, it's a duplication of the	2 3 4 5 6	and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain," International Journal of Clinical Medicine, 2014, by Dr. R. Bendavid, Dr. W. Lou, Dr. A. Koch and Dr. V. Iakovlev.
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2 3 4 5 6 7 8 9 10 11 12 13 14	A. Yes. I included all what I could at this stage, I mean, whatever I had. Q. Okay. And number two, is that essentially a duplication of the fully published article number one on your list? A. Well, it's a duplication of the title. So what happens with some conferences or other meetings, it's a bit an abstract. Abstract is accepted, it's published either in special journal issue, and then they make a decision, if you make an oral presentation, or you make a poster presentation. So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review	2 3 4 5 6 7 8 9 10 11 12 13 14	and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain," International Journal of Clinical Medicine, 2014, by Dr. R. Bendavid, Dr. W. Lou, Dr. A. Koch and Dr. V. Iakovlev UPON RESUMING AT 11:03 THE VIDEOGRAPHER: Here begins media number two in the deposition of Dr. Vladimir Iakovlev. We're back on the record at 11:03 a.m. BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel. MR. ORENT: Thank you. BY MS. BYARD:
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. I included all what I could at this stage, I mean, whatever I had. Q. Okay. And number two, is that essentially a duplication of the fully published article number one on your list? A. Well, it's a duplication of the title. So what happens with some conferences or other meetings, it's a bit an abstract. Abstract is accepted, it's published either in special journal issue, and then they make a decision, if you make an oral presentation, or you make a poster presentation. So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review process, and then there is a decision how you present it. So it becomes presented twice. One in the form of abstract, and then one in the form of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain," International Journal of Clinical Medicine, 2014, by Dr. R. Bendavid, Dr. W. Lou, Dr. A. Koch and Dr. V. Iakovlev UPON RESUMING AT 11:03 THE VIDEOGRAPHER: Here begins media number two in the deposition of Dr. Vladimir Iakovlev. We're back on the record at 11:03 a.m. BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel. MR. ORENT: Thank you. BY MS. BYARD: Q. Doctor, do you recognize Exhibit 1197? A. Yes. Q. What is it?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes. I included all what I could at this stage, I mean, whatever I had. Q. Okay. And number two, is that essentially a duplication of the fully published article number one on your list? A. Well, it's a duplication of the title. So what happens with some conferences or other meetings, it's a bit an abstract. Abstract is accepted, it's published either in special journal issue, and then they make a decision, if you make an oral presentation, or you make a poster presentation. So then abstract is duplicated as oral presentation or poster presentation, because abstract you describe your work to the peer review process, and then there is a decision how you present it. So it becomes presented twice. One in the form of abstract, and then one in the form of presentation. Q. Okay. So for all these articles	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	and Its Morphologic Background in the Etiology of Post-Herniorrhaphy Pain," International Journal of Clinical Medicine, 2014, by Dr. R. Bendavid, Dr. W. Lou, Dr. A. Koch and Dr. V. Iakovlev UPON RESUMING AT 11:03 THE VIDEOGRAPHER: Here begins media number two in the deposition of Dr. Vladimir Iakovlev. We're back on the record at 11:03 a.m. BY MS. BYARD: Q. Doctor, I'll hand you what's been marked as 1197. Counsel. MR. ORENT: Thank you. BY MS. BYARD: Q. Doctor, do you recognize Exhibit 1197? A. Yes. Q. What is it? A. It's published article, co-authored by me. Q. So these other doctors listed on

	Page 82		Page 84
1	Q. Do these doctors use mesh and	1	A. That's correct.
2	hernia repair, to your knowledge?	2	Q. Would you describe this study as
3	A. Yes. Except for Dr. Lou, she's a	3	having been controlled through the use of virgin
4	statistician.	4	tissue and scar tissue?
5	Q. Presently Dr. Bendavid continues	5	A. No. As I said, control is a
6	to use polypropylene mesh for the treatment of	6	specific statistical term for clinical prospective
7	abdominal hernia repair; correct?	7	studies.
8	MR. ORENT: Objection.	8	Q. How would you describe this study
9	THE WITNESS: No. Actually, he uses	9	then?
10	native tissue to repair. He takes out meshes.	10	A. This was a prospective study.
11	BY MS. BYARD:	11	Q. Why was it important for the study
12	Q. Did there come a time when his	12	to use virgin tissue, scar tissue, and explanted
13	practice changed in that regard, to your knowledge?	13	mesh specimens in comparison to one another?
14	A. It depends. I mean, in some	14	A. There were two questions. First
15	patients you just have no choice. You have to use,	15	question was, if nerve ingrowth occurs in the mesh
16	like, um, central large defects.	16	which has been reported even before this paper.
17	Q. So he makes a patient your	17	And the second question was, what's the
18	understanding is that Dr. Bendavid makes a	18	nerve density in comparison with virgin tissue and
19	patient-specific determination about whether or not	19	scar without mesh. If mesh inhibits nerve
20	to use polypropylene mesh in hernia repair?	20	ingrowth; and if it inhibits, to what degree. Sort
21	MR. ORENT: Objection.	21	of establishes a baseline for these parameters.
22	THE WITNESS: That's correct.	22	 Q. So you used virgin tissue and scar
23	BY MS. BYARD:	23	tissue in order to establish a baseline for the
24	Q. Is the same true for Dr. Andreas	24	comparison to mesh that you were making in terms of
25	Koch?	25	nerve proliferation in tissue, correct?
	Page 83		Page 85
1	A. Koch.	1	A. Mesh and scar were more of a
2	MR. ORENT: Objection.	2	controls in this study. I mean virgin, was more of
3	BY MS. BYARD:	3	a control. But baseline was between all of those
4	Q. Koch?	4	three types of tissue.
5	A. Yes.	5	Q. So explain to the jury what you
6	Q. Okay. Explain to the jury what a	6	mean by "control".
7	controlled study is.	7	MR. ORENT: Objection.
8	A. Where is the jury?	8	THE WITNESS: I didn't mean control.
9	Q. (Indicates.)	9	Where did I say "control"? Control, you mean
10	A. Okay. You mean controlled	10	control samples?
11	clinical study?	11	BY MS. BYARD:
12	Q. Just in general, what a controlled	12	Q. Yes.
13	study is. Whether it's in a clinical setting, or	13	A. Sorry, I misunderstood you.
14	in your laboratory?	14	Control sample is a sample which is
15	A. "Controlled" usually implies to a	15	used for comparison, something which implies
16	clinical study, so if it's in a laboratory it	16	doesn't have any changes.
17	wouldn't be controlled.	17	Something neutral, normal, or something
18	Controlled is a prospective study where	18	which has been exposed to only methodology
19	patients are registered and specific statistical	19	manipulations, rather than biological processes
20	requirements for this.	20	which are being studied.
21	Q. In this study with Dr. Bendavid,	21	BY MS. BYARD:
22	you used ten specimens, in three groups; in each of	22	Q. And similarly, you've used scar
23	three groups. You looked at virgin tissue, you	23	tissue in this study as a control to understand if
24	looked at scar tissue, and you looked at explanted	24	there were differences related to the mesh?
25	mesh from the posterior inguinal wall; correct?	25	A. Yes. So mesh is encapsulated by

Page 86 Page 88 1 scar tissue. So control for scar around and inside 1 for nerve density, nerve size, and nerve and vessel 2 the mesh would be scar without mesh. So the same 2 ingrowth, correct? 3 area, surgical procedure, all of those are 3 A. That's correct. Well, we assessed 4 4 variables are the same, except one group has mesh the specimen, so we observed what was abnormal in 5 5 and the other group doesn't have mesh. the microscope. So the main hypothesis and main 6 6 Q. Other terms that are used to focus was nerve ingrowth, but then there were other 7 7 describe study designs include "randomized studies" microscopic findings within mesh specimens which 8 or "blinded studies"; are you familiar with those 8 were observed. 9 9 Q. You found that there were no 10 10 A. Yes, I am. significant differences in nerve density between 11 11 Q. Is it fair to say that this was a virgin scar and mesh samples, correct? 12 12 controlled study, but not randomized or blinded? A. Yeah, that's correct. In that 13 13 A. You're just using it in different -sample size, there was no statistical significant 14 randomized, controlled studies -- these are all 14 difference. 15 clinical terms, specific statistical methods for 15 Q. You concluded that the presence of 16 clinical prospective studies when a drug is tested 16 mesh does not significantly affect nerve density, 17 17 or a new device is tested. So the patients are right? 18 randomized before they are given treatment. And 18 A. It's the same statement as before. 19 then they follow this cohorts. And then there is 19 Q. You concluded that -- you 20 statistical methods to follow that, and there are 20 concluded, though, that the nerves and their 21 21 specific requirements for that. terminal ends were in a volnerable position about 22 22 In this case, it's not applicable, the mesh and within its pores? 23 23 because there were no new device, no new medication A. That was additional findings, 24 24 introduced. And the randomization is done before because we observed changes of the scar tissue 25 25 the device is being inserted, or new medication is within the mesh, because it was different from the Page 87 Page 89 1 1 scar without the mesh. given. You cannot randomize it after. So it's 2 Q. How so? 2 completely different, we are talking about 3 completely different scenarios. 3 A. It's all described in the paper. 4 Q. Well, and it wasn't blinded in the 4 There are vascular congestion, edema, inflammation, 5 5 sense that you knew whether the specimen that you foreign body type, chronic lymphoplasmacytic 6 6 inflammation. were looking at was native tissue or virgin tissue, 7 7 whether it was scar tissue or whether it was mesh, (Reporter sought clarification.) 8 8 correct? A. Foreign body type inflammation, 9 A. Blinded, again, it's more of a 9 and chronic lymphoplasmacytic inflammation. 10 clinical terminology when you do controlled 10 MR. ORENT: L-Y-M-P-H-O-P-L-A-S-M-A-C-Y-T-I-C. 11 11 studies. BY MS. BYARD: 12 So either patients are blinded, or 12 Q. What did you mean by "in a 13 13 researchers are blinded. I mean, there was a vulnerable position"? 14 degree of blindness in this study. But again, 14 A. In a pathologically changed 15 talking about completely different statistical 15 tissue, mainly it is compartmentalization of the 16 scenarios, completely different approaches. 16 mesh. So what happens, the scar tissue within the 17 Q. What do you mean by, there was a 17 mesh is divided into compartments. So, 18 degree of blinded in this study? 18 essentially, there are little gates or bottlenecks 19 A. When I was examining them, I was 19 in the mesh. And this mainly causes the problem. 20 examining them without knowledge of other clinical 20 Because it's compartment, it's enclosed 21 21 variables. I could clearly see that there's no compartment. Like tooth pulp, this is best 22 mesh in it: if it's scar or not scar. 22 analogy. It gets inflamed; you feel pain. 23 But then I didn't know if there were 23 Q. You didn't write here, though, 24 comorbidities, other possible clinical variables. 24 that the compartmentalization of nerves in mesh is 25 Q. So here you examined the samples 25 what caused clinical complications in these

	Page 90		Page 92
1	patients. You wrote that they were in a vulnerable	1	what I think is well, usually, it is what is
2	position, correct?	2	available.
3	A. In the text, I think there is	3	If it's a large POP device, I submit
4	compartmentalization discussion.	4	representative sections. Usually not more than
5	Q. Well, what you wrote, though, was	5	three blocks. I never needed to submit more
6	that nerve receptors were exposed to potential	6	tissue. Either I submitted everything, or it was
7	mechanical and chemical factors: Scarring,	7	satisfactory for examination to submit what I
8	entrapment, compression, tugging, deformation,	8	submitted first time.
9	contraction, hypoxia/acidosis, inflammation and	9	BY MS. BYARD:
10	edema. That's what you wrote; correct?	10	Q. What do you mean by
11	A. That's an abstract.	11	"representative sections"?
12	MR. ORENT: Objection.	12	A. Representative of the sample.
13	THE WITNESS: You're reading an	13	Q. And how do you determine that?
14	abstract. I'm saying that there is discussion	14	A. According to my training and
15	longer in the text.	15	experience.
16	BY MS. BYARD:	16	Q. Are you taking, though, when you
17	Q. Is that what appears in the	17	examine transvaginal mesh specimens, are you taking
18	abstract, sir?	18	samples or sections that you determine are
19	A. You just read it, yes.	19	representative based on your training?
20	Q. In the introduction, the last	20	A. Yes.
21	sentence reads:	21	MR. ORENT: Objection.
22	"The mesh in question is	22	BY MS. BYARD:
23	polypropylene, the most widely used	23	Q. In the second full paragraph under
24	polymer in hernia repair." Correct?	24	methods you write:
25	A. That's correct.	25	"If a peripheral nerve was seen
			II a portprioral not to that seem
	- 01		
	Page 91		Page 93
1	Q. There's a discussion here under	1	Page 93 an imaginary line connecting the
1 2		1 2	_
	Q. There's a discussion here under		an imaginary line connecting the
2	Q. There's a discussion here under your methods, that the mesh samples	2	an imaginary line connecting the outermost points of adjacent mesh
2 3	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were	2	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve
2 3 4	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and	2 3 4	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore."
2 3 4 5	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not	2 3 4 5	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right?
2 3 4 5 6	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two	2 3 4 5 6	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct.
2 3 4 5 6 7	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken	2 3 4 5 6 7	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct. Q. Tell me what you mean by
2 3 4 5 6 7 8	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken until penetration was directed."	2 3 4 5 6 7 8	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct. Q. Tell me what you mean by "imaginary line"?
2 3 4 5 6 7 8 9	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken until penetration was directed." Do you see that?	2 3 4 5 6 7 8	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct. Q. Tell me what you mean by "imaginary line"? A. Do you want me to draw or that
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2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken until penetration was directed." Do you see that? A. "Detected". Q. Thank you. Do you see that? A. Yes. Q. Did you perform the same type of sampling for microscopic evaluation in your examinations of transvaginal mesh?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct. Q. Tell me what you mean by "imaginary line"? A. Do you want me to draw or that would be easier. Q. We might do that later. Can you try and explain it to me in words? A. Essentially this describes the boundaries of a mesh area, area which is occupied by mesh, which by definition would be new tissue.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken until penetration was directed." Do you see that? A. "Detected". Q. Thank you. Do you see that? A. Yes. Q. Did you perform the same type of sampling for microscopic evaluation in your examinations of transvaginal mesh? A. No, there was no need. The nerve density is so much higher in transvaginal meshes,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct. Q. Tell me what you mean by "imaginary line"? A. Do you want me to draw or that would be easier. Q. We might do that later. Can you try and explain it to me in words? A. Essentially this describes the boundaries of a mesh area, area which is occupied by mesh, which by definition would be new tissue. Tissue which appeared after the mesh was placed. Q. So when you look at a slide, you
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken until penetration was directed." Do you see that? A. "Detected". Q. Thank you. Do you see that? A. Yes. Q. Did you perform the same type of sampling for microscopic evaluation in your examinations of transvaginal mesh? A. No, there was no need. The nerve density is so much higher in transvaginal meshes, that pretty much very small piece would contain it.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct. Q. Tell me what you mean by "imaginary line"? A. Do you want me to draw or that would be easier. Q. We might do that later. Can you try and explain it to me in words? A. Essentially this describes the boundaries of a mesh area, area which is occupied by mesh, which by definition would be new tissue. Tissue which appeared after the mesh was placed. Q. So when you look at a slide, you see either a clear space or a whole space where you
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. There's a discussion here under your methods, that the mesh samples "The mesh specimens were sampled initially by two blocks, and then if nerve ingrowth was not detected within the initial two blocks, additional blocks were taken until penetration was directed." Do you see that? A. "Detected". Q. Thank you. Do you see that? A. Yes. Q. Did you perform the same type of sampling for microscopic evaluation in your examinations of transvaginal mesh? A. No, there was no need. The nerve density is so much higher in transvaginal meshes, that pretty much very small piece would contain it. Q. So unlike this study on hernia mesh, for transvaginal mesh you didn't initially sample the specimens to determine if you could detect nerve ingrowth or not? MR. ORENT: Objection.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	an imaginary line connecting the outermost points of adjacent mesh filaments, it was recorded as nerve ingrowth into the mesh pore." Right? A. That's correct. Q. Tell me what you mean by "imaginary line"? A. Do you want me to draw or that would be easier. Q. We might do that later. Can you try and explain it to me in words? A. Essentially this describes the boundaries of a mesh area, area which is occupied by mesh, which by definition would be new tissue. Tissue which appeared after the mesh was placed. Q. So when you look at a slide, you see either a clear space or a whole space where you determine that the mesh was or is and can't be seen, right? MR. ORENT: Objection. THE WITNESS: What I see in the microscope, I see cross-sections of the filaments,

Page 94 Page 96 1 the mesh filaments. Therefore, anything inside 1 Q. And this same process that you 2 this boundaries, is new tissue which was generated 2 describe here in this study of drawing an imaginary 3 after mesh was placed. 3 line connecting the outermost points of the 4 It was an artificial sort of 4 adjacent mesh filaments, is the same process by 5 distinction for us to understand during this study, 5 which you determined the shape of the mesh when 6 6 which nerves were new, new innervation or looking at transvaginal specimens, correct? 7 7 reinnervation. And which nerves could have been A. No, I don't understand your 8 trapped in the scar which was expanding into normal 8 question. Shape in nerves -- they are different 9 tissue. 9 10 10 BY MS. BYARD: Q. Okay. Let me take it then the way 11 Q. To identify when looking -- let me 11 that you've presented it. 12 12 This same process that you describe in start over. 13 the study of drawing an imaginary line connecting 13 When looking at transvaginal mesh 14 slides under microscope, you have to draw the same 14 the outermost points of adjacent mesh filaments, in 15 imaginary line connecting the outermost points of 15 order to determine whether nerves were there 16 16 the adjacent mesh filaments in order to record beforehand, or whether they grew into the mesh, is 17 17 whether nerves are ingrown in the mesh, are whether the same method that you applied to your analysis 18 they were preexisting, correct? 18 of transvaginal mesh specimens in the litigation, 19 19 A. Yes, I mean this would be a very correct? 20 strict criteria. Because some nerve branches just 20 A. In litigation, I describe nerve 21 outside of the imaginary line can still be new 21 involvement. I mean, they might be ingrown; they 22 ones. But, I mean, anything beyond those lines is 22 might be just outside. 23 As I said, diagnostically, if the nerve new, by definition. 23 24 But the one I assess, I make a 24 is affected, it could be outside of the imaginary 25 line. It can be trapped in the scar tissue or 2.5 distinction. Especially if I collect data for Page 95 Page 97 research product. But for symptoms as a diagnostic 1 1 around 2 tool, it doesn't have much significance. 2 I think it is a little artificial to 3 Because as I said, I mean, nerves 3 hook on this imaginary line. It was done for the 4 right -- just outside that line, can be affected to 4 research project. As I said, diagnostically, what 5 5 the same degree as -- it might be microns matters is, if there is an innervation in the 6 6 tissue, in that tissue. That's important. difference, here or there, so -- but that was 7 7 important for this study, to understand it as Q. To determine whether or not a 8 8 nerve had ingrown into mesh, though, when you were diagnostically this doesn't have much significance. 9 9 Q. Do you know, or did your -- I'm looking at transvaginal mesh specimens, you had to 10 sorry, let me start over. 10 draw this imaginary line connecting the outermost 11 points of adjacent mesh filaments? 11 Did your research here, look at how, 12 12 diagnostically, nerves growing outside of mesh or A. If I want to call it ingrown, yes, 13 13 it's important. But diagnostically, is it -- if preexisting nerves, compared in terms of clinical only ingrown nerves are important for diagnostic 14 complications to nerves growing within the mesh? 14 15 15 A. In this study? purposes, this is not correct. 16 Q. (Nods.) 16 Because ingrown nerves which are inside 17 A. In this study, we, as I said, 17 the compartment, they are much deeper. But at the 18 same time, if a nerve is just outside, it branches, 18 establish baseline. 19 19 and then supplies nerve endings, small branches in Q. So the answer to my question is, 20 "no, you did not," right? 20 the tissue inside. MR. ORENT: Objection. 21 21 Q. Please listen to my question, sir. 22 THE WITNESS: Well, you see that there 22 In order to determine whether nerve was 23 is no specific correlation with clinical 23 ingrown in mesh, when examining transvaginal mesh

specimens, you had to draw this same imaginary line

that you describe in your study with Bendavid,

24

25

24

25

presentation in this specific study.

BY MS. BYARD:

	Page 98		Page 100
1	connecting the outermost points of adjacent mesh	1	MR. ORENT: Objection.
2	filaments, didn't you?	2	THE WITNESS: No.
3	MR. ORENT: Objection. Asked and	3	BY MS. BYARD:
4	answered. Moreover, Dr. Iakovlev is entitled to	4	Q. And so you didn't adjust
5	give a full and complete response to the questions	5	calculate an adjustment ratio, and your examination
6	and he will continue to do so and	6	and analysis of transvaginal mesh for litigation,
7	MS. BYARD: Please limit your	7	correct?
8	objections to form, sir.	8	MR. ORENT: Objection.
9	MR. ORENT: Asked and answered.	9	THE WITNESS: Again, we are going from
10	THE WITNESS: As I said, in the	10	research from scientific question to diagnostic
11	description if I say ingrown, I use this imaginary	11	processes.
12	line. But diagnostically, this has not it	12	I don't base my opinion on adjustment
13	doesn't have much significance. Because what I do	13	ratios or on the specifics of what I did in the
14	in diagnostically, I try to estimate or assess if	14	research part. I don't
15	the tissue is innervated. That's what important.	15	BY MS. BYARD:
16	BY MS. BYARD:	16	Q. My only question is whether you
17	Q. But whether you determine that a	17	did it?
18	nerve was ingrown, depends completely on whether it	18	A. I never used it. It was only used
19	lies within the parameters of this imaginary line	19	once for this specific study, for specific
20	that you've drawn?	20	question. It wasn't diagnostic question. It was
21	MR. ORENT: Objection. Asked and	21	more of a mathematical question.
22	answered.	22	Q. I want to turn to page 802 of 1197.
23	THE WITNESS: Ingrown where? Ingrown	23	The last two full sentences before the
24	in the scar, or ingrown inside the mesh?	24	figures read:
25	BY MS. BYARD:	25	"The branches located at the
23	BT MS. BTARD.	23	The branches located at the
	- 00		
	Page 99		Page 101
1	Q. Ingrown inside the mesh, please.	1	Page 101 mesh interface tended to have an
1 2	_	1 2	
	Q. Ingrown inside the mesh, please.		mesh interface tended to have an
2	Q. Ingrown inside the mesh, please.A. If it's ingrown inside the mesh	2	mesh interface tended to have an orientation parallel to the mesh
2 3	Q. Ingrown inside the mesh, please. A. If it's ingrown inside the mesh and I make a statement	2 3	mesh interface tended to have an orientation parallel to the mesh plane."
2 3 4	Q. Ingrown inside the mesh, please. A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection.	2 3 4	mesh interface tended to have an orientation parallel to the mesh plane." A. That's correct.
2 3 4 5	Q. Ingrown inside the mesh, please. A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond	2 3 4 5	mesh interface tended to have an orientation parallel to the mesh plane." A. That's correct. Q. "Some branches showed a coarse
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2 3 4 5 6 7	Q. Ingrown inside the mesh, please. A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it	2 3 4 5 6 7	mesh interface tended to have an orientation parallel to the mesh plane." A. That's correct. Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90
2 3 4 5 6 7 8	Q. Ingrown inside the mesh, please. A. If it's ingrown inside the mesh and I make a statement MR. ORENT: Objection. THE WITNESS: that it was beyond that imaginary line, diagnostically it does not matter. Because it can be ingrown in the scar, it innervates the tissue.	2 3 4 5 6 7 8	mesh interface tended to have an orientation parallel to the mesh plane." A. That's correct. Q. "Some branches showed a coarse angled to the mesh plane, and nine out of the ten specimens, 90 percent, showed penetration of
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Page 102 Page 104 A. No, this is not my testimony. 1 Nerve branch goes along the plane, and 1 2 then there are small branches going into the mesh 2 It's higher. And on an average, the last time I 3 and they innervate inside tissue. It's logical 3 calculated, it's about six times higher. What is 4 an average number of nerves I see, and I'm talking biological. 4 5 5 about densities, which was about six times higher. Q. Is this same finding -- let me 6 6 Number of nerves I see, I don't know start over. 7 Were your findings about the 7 now. It's much higher. I mean, it's definitely 8 orientation of the branches of nerves located at 8 not one to three, it's about beyond ten or so. 9 the mesh interface similar for transvaginal mesh as 9 And then it depends, I mean, what 10 you've described here for hernia mesh? 10 device we are talking about. Sling, slings tend to have smaller specimens. POP devices, it might be 11 A. Transvaginal mesh is different 11 12 12 because there are no anatomical planes. In the over a hundred of nerves that I see in one section, 13 hernia, in the anterior abdominal wall, you have 13 it depends. 14 layers which are separated by fascia, serrated 14 Q. So the way you went about arriving 15 muscle, so there are anatomical planes. 15 at this number for your valuation of hernia repair, 16 16 was to actually count the number of nerves per In transvaginal location, there is no 17 anatomical plane. Tissues just merge into each 17 specimen, correct? 18 18 other. The orientation of nerves is a little bit A. That's correct. 19 19 Q. And you haven't done that counting different, because in the anterior abdominal wall, 20 most of the nerves run parallel to supply further; 20 activity for transvaginal mesh specimens? 21 21 so the mesh is placed parallel. A. I have not. 22 In the transvaginal location, the nerve 22 MR. ORENT: Objection. 23 23 THE WITNESS: There are reports, branches are running to innervate mucosa. And the 24 mesh is placed perpendicular, so this is completely 24 completed surgical pathology reports with synoptic 25 a different anatomical structure. 25 data, and there is a full count. Page 103 Page 105 1 So in transvaginal meshes, they are all Again, it's not what I am basing my 2 2 over the place, and I did not see that predominance opinion, but this was done more for research 3 of parallel orientation. It's different anatomical 3 purpose later on. 4 structure. 4 BY MS. BYARD: 5 5 Q. You write that the number of Q. Okay. So in answer to my 6 nerves ingrown -- and I've switched to page 803. 6 question, you haven't done this type of overall 7 7 On page 803, the first full sentence you write: analysis of counting the nerves, the number of 8 8 "The number of nerves ingrown nerves that you see grown into mesh structure for 9 into the mesh structures range from 9 transvaginal mesh, right? 10 one to three per examined portion of 10 MR. ORENT: Objection. Asked and a specimen." 11 11 answered. 12 Correct? 12 THE WITNESS: I have done it. When the 13 13 complete surgical report is issued, it contains A. That's correct. 14 Q. Were your findings in examining 14 these numbers. 15 15 transvaginal mesh specimens similar to your BY MS. BYARD: 16 findings here on hernia mesh? 16 Q. Whose complete surgical report? 17 A. No. Densities are much higher in 17 A. There's some, I think I completed transvaginal meshes. About six times on average it to -- when I sign out a surgical pathology 18 18 19 19 report in St. Michael's system, I include full than in inguinal hernia. 20 Q. So when you see the number of 20 analysis for nerve report -- nerve densities. 21 21 nerves ingrown into mesh structures and hernia Q. So there are some cases where 22 repair ranging from one to three per examined 22 you've completed a complete St. Michael's surgical 23 portion of the mesh; the number would be closer to 23 pathology report and others where you haven't, 24 6 to 18 nerves per examined specimen for 24 correct? 25 25 transvaginal mesh? Is that your testimony? A. For most of this, I didn't have

1 time to complete the surgical pathology repo	106	Page 108
	orts. 1	question.
2 But you have at least one here, I thin		A. I've done it.
3 for Ms. Holland.	3	MR. ORENT: Objection.
4 MR. ORENT: Tab 1.	4	THE WITNESS: You asked me if I've done
5 BY MS. BYARD:	5	it for 120. I've done the count for those which
6 Q. I know what you're referring to	6	were completed cases.
7 and we'll look at that tomorrow.	7	I have stacks of cases at different
8 A. Okay.	8	stages of completion. It's work in progress for
9 Q. Take the time you need, I know	9	some of them. But with the cases completed,
what you're referring to, though.	10	altogether with a surgical pathology report, there
A. So how this is done, when I	11	is count. For each single specimen completed,
Q. That's okay, there's no question	12	there is count of nerves and nerve densities.
13 pending.	13	BY MS. BYARD:
MR. ORENT: That's the report you'	re 14	Q. And of the 25-plus cases we will
15 looking for?	15	talk about tomorrow, you have one example of that,
16 THE WITNESS: Yeah, the densities	s here, 16	right?
17 right there.	17	MR. ORENT: Objection. Misstates his
18 BY MS. BYARD:	18	testimony.
Q. So my question is focused on yo	our 19	THE WITNESS: Not example. One case is
20 analysis which case is that?	20	completed in that respect.
21 A. This one.	21	BY MS. BYARD:
22 MR. ORENT: Lucy Allen.	22	Q. Okay. And the range of the number
23 MS. BYARD: Okay.	23	of nerves ingrown into mesh structures for
24 (Reporter sought clarification).	24	transvaginal mesh in the 120 specimens that are
25 MR. ORENT: Lucy Allen.	25	detailed in your report, doesn't appear in your
Page	107	Page 109
1 And he's pointing to the line that	1	report, does it?
2 reads, "was it 59 branches?"	2	MR. ORENT: Objection.
3 BY MS. BYARD:	3	THE WITNESS: No, I didn't record it.
4 Q. Okay. So my question is focused	4	Because I'm not basing my opinion for that specific
5 on the 120 specimens that are talked about in	· I	for this specific purpose we are here today.
6 report.	6	BY MS. BYARD:
1	1 7	
7 You didn't perform an analysis of the		Q. Okay. And, Doctor, if there are
7 You didn't perform an analysis of the number of nerves in each individual specimen	of 8	reasons why things were included or not included,
7 You didn't perform an analysis of the 8 number of nerves in each individual specimen 9 those 120 that you examined, in order to arrive	of 8 e at 9	reasons why things were included or not included, your counsel can ask you about that. I just am
7 You didn't perform an analysis of the 8 number of nerves in each individual specimen 9 those 120 that you examined, in order to arrive 10 a range of averages of the number of branches	of 8 9 10	reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay?
You didn't perform an analysis of the number of nerves in each individual specimen those 120 that you examined, in order to arrive a range of averages of the number of branches ingrown into mesh structures for transvaginal	of 8 e at 9 mesh? 11	reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay? You conclude this paragraph on page 803
You didn't perform an analysis of the number of nerves in each individual specimen those 120 that you examined, in order to arrive a range of averages of the number of branches ingrown into mesh structures for transvaginal MR. ORENT: Objection.	of 8 e at 9 10 mesh? 11 12	reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay? You conclude this paragraph on page 803 of Exhibit 1197 by saying:
You didn't perform an analysis of the number of nerves in each individual specimen those 120 that you examined, in order to arrive a range of averages of the number of branches ingrown into mesh structures for transvaginal MR. ORENT: Objection. THE WITNESS: I have done for large	of 8 e at 9 10 mesh? 11 12 e 13	reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay? You conclude this paragraph on page 803 of Exhibit 1197 by saying: "These one to three ingrown
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You didn't perform an analysis of the number of nerves in each individual specimen those 120 that you examined, in order to arrive a range of averages of the number of branches ingrown into mesh structures for transvaginal MR. ORENT: Objection. THE WITNESS: I have done for large part of those. Those counts are done for large number of this specimens. BY MS. BYARD:	of 8 9 10 mesh? 11 12 12 13 14 15 16	reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay? You conclude this paragraph on page 803 of Exhibit 1197 by saying: "These one to three ingrown nerves into the pores constituted a median of 6.3 percent range, 2.17 percent to 15.8 percent of all
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You didn't perform an analysis of the number of nerves in each individual specimen those 120 that you examined, in order to arrive a range of averages of the number of branches ingrown into mesh structures for transvaginal MR. ORENT: Objection. THE WITNESS: I have done for large part of those. Those counts are done for large number of this specimens. BY MS. BYARD: Q. That doesn't appear in your report, does it? A. Which, which report? Q. In your report, Exhibit 197? A. Which one? I don't understand. Q. Or 196.	of 8 9 10 mesh? 11 12 13 14 15 16 17 18 19 20 21 22 23 24	reasons why things were included or not included, your counsel can ask you about that. I just am asking you if it's there or not, okay? You conclude this paragraph on page 803 of Exhibit 1197 by saying: "These one to three ingrown nerves into the pores constituted a median of 6.3 percent range, 2.17 percent to 15.8 percent of all nerves seen within the examined tissue." A. That's correct. Q. Here you compared the number of nerves ingrown into pores with the number of nerves that were seen in the examined tissue as a whole?

Page 110 Page 112 1 Q. And compared to the number of 1 scientific question, I will complete it. But 2 nerves that were in the examined tissue overall, 2 again, the conclusions in this paper were not based 3 the number of nerves that were grown into pores, 3 on this number. This number was provided for 4 4 was a median of 6.3 percent with a range of 2.17 to readers to understand what is going on. 5 5 15.8 percent, correct? BY MS. BYARD: 6 A. That's correct. 6 Q. Could you tell me, sitting here 7 7 Q. Have you performed this same today, what percentage of nerves you would expect 8 statistical analysis for the transvaginal mesh 8 to be ingrown compared to not ingrown and present 9 specimens? 9 in tissue for transvaginal mesh? 10 A. For those I completed test, I 10 A. At least the same as in hernia. 11 mean, it's somewhere in the spreadsheet. I started 11 As I said, likely several fold higher as well, 12 testing that as well. But it's only when the nerve 12 because of difference in anatomical orientation. count is completed that I can do it. 13 13 As I said, in transvaginal location, 14 Q. So it's not in your report, is it? 14 there are branches that going to innervate mucosa, 15 A. No. It has no diagnostic 15 so they're perpendicular to the mesh. So I'm 16 significance. One nerve is enough. I mean, if you 16 expecting to see much higher percentage. 17 17 have one nerve in the tooth and it hurts, it's just Q. That's a working hypothesis at 18 one nerve is enough. 18 this point, but not a scientific conclusion arrived MS. BYARD: Object and move to strike at through the same type of statistical analysis --19 19 20 after the words, "No, it's not in the report." 20 MR. ORENT: Objection. MR. ORENT: Oppose. 21 21 BY MS. BYARD: 22 BY MS. BYARD: 22 Q. -- right? 23 23 A. Yes, this is. But it will be at Q. Do you know how the percentage of 24 24 nerve ingrowth in transvaginal mesh samples within least 6.3 percent. Again, diagnostically, it's mesh structures compares to the number of nerves in 25 irrelevant. For specific patients, for specific 25 Page 111 Page 113 transvaginal mesh specimens overall? 1 purpose we're here today. 1 2 MR. ORENT: Objection. 2 Q. And here you have this nerve 3 THE WITNESS: I think I answered that 3 assessment data Table 1 on page 804. 4 generally, density is about six times higher. I 4 A. Yes. 5 mean, it depends on how you group those devices. 5 Q. And the transvaginal specimen 6 If you split them into slings versus POP devices, 6 analysis that you have done, did you compare virgin 7 7 but generally several fold higher. tissue and scar tissue with actual samples? 8 BY MS. BYARD: 8 A. No --9 Q. That's true across the tissue 9 MR. ORENT: Objection. 10 specimen, though, correct? 10 THE WITNESS: -- I mean I don't understand why you're asking these questions. And 11 A. Transvaginal. If we compare 11 12 12 transvaginal versus inguinal hernia, that's true. I didn't complete -- this was different study and 13 just, I mean, this is -- again, as I said, this is Q. What I am focused on now is the 13 14 amount of nerves growing into the mesh pores 14 not diagnostically relevant. 15 compared to the amount of nerves overall. And we 15 MS. BYARD: Object and move to strike 16 know from your study that it's around 6.3 percent 16 everything besides, "no." 17 for inguinal hernia repair mesh. 17 MR. ORENT: So are you suggesting by 18 18 I'm asking if you have a percentage for your repeated motions to strike, that he's not 19 19 me of the percentage rate of nerve ingrowth into entitled to give a full answer? 20 compartmentalized pores for transvaginal mesh as 20 MS. BYARD: I don't think I have to 21 compared to the number of tissues overall in the 21 answer your question for the basis of my motion. 22 specimens that you've examined? 22 I just -- my questions are simple, and 23 MR. ORENT: Objection. 23 we're going to be here a long time if I can't just 24 THE WITNESS: As I said, that work is 24 get answers to my questions. 25 25 MR. ORENT: I think that's what he is not completed. It is not done yet. If there is a

	Page 114		Page 116
1	doing. And I think you're going beyond the scope	1	BY MS. BYARD:
2	of what he's even intending to offer at trial. So	2	Q. That's not in your report?
3	if we stick to his opinions, we can move fast, too.	3	A. That's for research, the report is
4	But, Doctor, you can go ahead and keep	4	diagnostic. Again, the same issue. We are mixing
5	answering your questions as you see fit.	5	up unmixable things. Research and diagnostic work.
6	BY MS. BYARD:	6	Q. That's not in your report is it,
7	Q. So here for this study, you've	7	sir?
8	used control samples, haven't you?	8	MR. ORENT: Objection.
9	A. For this study, yes.	9	THE WITNESS: There is no statistics of
10	Q. You used the control sample in	10	comparison at all, because my reports are
11	virgin tissue?	11	diagnostic reports, and this is research.
12	MR. ORENT: Objection. Asked and	12	BY MS. BYARD:
13	answered.	13	Q. So you agree with me it doesn't
14	THE WITNESS: Yes.	14	appear in your report?
15	BY MS. BYARD:	15	MR. ORENT: Objection. Asked and
16	Q. You used another control sample in	16	answered for the fourth time.
17	scar tissue, correct?	17	THE WITNESS: There was no research
18	MR. ORENT: Objection. Asked and	18	methodology or the reports are not research
19	answered.	19	project. They are reports.
20	THE WITNESS: Scar tissue was control	20	BY MS. BYARD:
21	and at the same time, it was a test group depending	21	Q. So the answer to my question is,
22	on how we compare them.	22	no, that control group in virgin tissue is not set
23	BY MS. BYARD:	23	forth or analyzed in your report in the litigation?
24	Q. In your report on your 120	24	MR. ORENT: Objection.
25	specimens for transvaginal mesh, you don't have a	25	THE WITNESS: It's not mentioned, but I
	specimens for dame raginal mesh, you don't have a	23	THE WITNESS. It's not mentioned, but I
	Page 115		D 110
	1490 113		Page 117
1	control group in virgin tissue?	1	know about the mesh tissue, or human body
1 2		1 2	
	control group in virgin tissue?		know about the mesh tissue, or human body interactions based on this study. So in order to produce this report, I
2	control group in virgin tissue? A. This is research. This is	2	know about the mesh tissue, or human body interactions based on this study. So in order to produce this report, I used my knowledge, which I gained through my
2	control group in virgin tissue? A. This is research. This is diagnostic work. We are mixing things which are	2 3	know about the mesh tissue, or human body interactions based on this study. So in order to produce this report, I
2 3 4	control group in virgin tissue? A. This is research. This is diagnostic work. We are mixing things which are completely unmixable. I just don't understand why	2 3 4	know about the mesh tissue, or human body interactions based on this study. So in order to produce this report, I used my knowledge, which I gained through my training, through this study and other studies, and then I make conclusions in diagnostic report. I
2 3 4 5	control group in virgin tissue? A. This is research. This is diagnostic work. We are mixing things which are completely unmixable. I just don't understand why we are doing this.	2 3 4 5	know about the mesh tissue, or human body interactions based on this study. So in order to produce this report, I used my knowledge, which I gained through my training, through this study and other studies, and then I make conclusions in diagnostic report. I could not put everything which I know or which
2 3 4 5 6	control group in virgin tissue? A. This is research. This is diagnostic work. We are mixing things which are completely unmixable. I just don't understand why we are doing this. Q. Please answer my question.	2 3 4 5 6	know about the mesh tissue, or human body interactions based on this study. So in order to produce this report, I used my knowledge, which I gained through my training, through this study and other studies, and then I make conclusions in diagnostic report. I
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. This is research. This is diagnostic work. We are mixing things which are completely unmixable. I just don't understand why we are doing this. Q. Please answer my question. MR. ORENT: Objection. Asked and answered. THE WITNESS: This is research. This is diagnostic work. Can you repeat the question so I understand what we are talking about, research or diagnosis? MS. BYARD: Would you mind reading back my question, Madam Court Reporter? REPORTER'S NOTE: Whereupon the question was read back as follows: "In your report on your 120 specimens for transvaginal mesh, you don't have a control group in virgin tissue?" MR. ORENT: Objection. THE WITNESS: I do. There are samples in St. Michael's Hospital of transvaginal mucosa	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	know about the mesh tissue, or human body interactions based on this study. So in order to produce this report, I used my knowledge, which I gained through my training, through this study and other studies, and then I make conclusions in diagnostic report. I could not put everything which I know or which or research studies I've done and the reports. BY MS. BYARD: Q. Have you done an analysis of nerve assessment data on vaginal virgin tissue? MR. ORENT: Objection. THE WITNESS: As I said, it's work in progress. It will be done when I complete. BY MS. BYARD: Q. To date, it hasn't been completed? MR. ORENT: Objection. THE WITNESS: No. BY MS. BYARD: Q. And the same thing is true for vaginal scar tissue, correct? A. As I said, it was not a question for the reports. The reports describe pathological

	Page 118		Page 120
1	We're talking about research questions.	1	BY MS. BYARD:
2	Sometimes it's question which is not relevant	2	Q. In terms of the number of nerves
3	specifically to diagnostic process.	3	present in tissue specimens density?
4	Q. The answer to my question is that,	4	A. My expectation is that the scar
5	no, that analysis has not been completed to date,	5	outside of the mesh would have about the same nerve
6	right?	6	density as an irregular scar from after any
7	MR. ORENT: Objection.	7	procedure.
8	THE WITNESS: The answer is, yes, I	8	In regards to innervation inside the
9	have not completed the analysis of transvaginal	9	mesh, it will be somewhat lower than innervation
10	meshes for research purpose.	10	outside. But again, it's not clinically relevant
11	BY MS. BYARD:	11	because the fact that it can ingrow, that's the
12	Q. And I'm focusing on an analysis of	12	most important clinical question.
13	vaginal scar tissue.	13	Q. And again, whether or not the
14	MR. ORENT: Is there a question there?	14	number of nerves that ingrow at the mesh is lower,
15	BY MS. BYARD:	15	or whether it's statistically significantly lower,
16	Q. Same question for vaginal scar	16	is an open hypothesis at this point, true?
17	tissue.	17	MR. ORENT: Objection.
18	MR. ORENT: Objection to form.	18	THE WITNESS: I don't understand why we
19	THE WITNESS: That, that's correct.	19	are asking this. I mean, diagnostic process is
20	BY MS. BYARD:	20	BY MS. BYARD:
21	Q. You write that you:	21	Q. Sir, you don't need to agree with
22	"Detected no indication that	22	my questions or why I'm asking them
23	the scar around and within the mesh	23	MR. ORENT: Excuse me. He's answer
24	has significantly lower innervation	24	BY MS. BYARD:
25	than an ordinary scar." Correct?	25	Q you just need to answer them.
	Page 119		Page 121
1	A. That's correct.	1	MR. ORENT: Counsel, he's entitled to
2	Q. Are those same findings true for	2	finish. The way this process works is, you ask a
3	transvaginal mesh?	3	question, he answers. You don't cut him off midway
4	A. As I said, I mean, we to answer	4	through his answer.
5	these questions which are not relevant to	5	He's entitled to finish his answer,
6	diagnostic process, you would have to compare	6	then you can say whatever you want to say.
7	vaginal scar and the scar in around meshes.	7	Doctor?
8	Q. And that work has not been	8	MS. BYARD: If you wouldn't mind,
9	completed to date, correct?	9	Counsel, I think it would be productive for you to
10	A. It has not been completed.	10	provide some guidance to the witness about not
11	Q. Based on your observations to	11	disputing why I'm asking a question.
12	date, do you expect that the innervation within a	12	MR. ORENT: Well, if he doesn't
13	mesh scar conglomerate is the same as within	13	understand, I think he's trying to understand where
14	vaginal scarring?	14	this fits and so that he can answer the question.
15	MR. ORENT: Can you repeat that or read	15	I don't think he's trying to be difficult.
16	that one back?	16	But, Doctor, if you could answer.
		17	THE WITNESS: So my response is because
17	REPORTER'S NOTE: Whereupon, the	1 1 ^	as far as I understand, we're talking about the
17 18	pending question was read back as follows:	18	-
17 18 19	pending question was read back as follows: "Based on your observations to	19	conclusions I derived based on my training,
17 18 19 20	pending question was read back as follows: "Based on your observations to date, do you expect that the	19 20	conclusions I derived based on my training, knowledge, experience and the research included in
17 18 19 20 21	pending question was read back as follows: "Based on your observations to date, do you expect that the innervation within a mesh scare	19 20 21	conclusions I derived based on my training, knowledge, experience and the research included in this one.
17 18 19 20 21 22	pending question was read back as follows: "Based on your observations to date, do you expect that the innervation within a mesh scare conglomerate is the same within	19 20 21 22	conclusions I derived based on my training, knowledge, experience and the research included in this one. But it appears that you equate research
17 18 19 20 21 22 23	pending question was read back as follows: "Based on your observations to date, do you expect that the innervation within a mesh scare conglomerate is the same within vaginal scarring?"	19 20 21 22 23	conclusions I derived based on my training, knowledge, experience and the research included in this one. But it appears that you equate research with the diagnostic process. Whatever I have done
17 18 19 20 21 22	pending question was read back as follows: "Based on your observations to date, do you expect that the innervation within a mesh scare conglomerate is the same within	19 20 21 22	conclusions I derived based on my training, knowledge, experience and the research included in this one. But it appears that you equate research

	Page 122		Page 124
1	BY MS. BYARD:	1	nerves." Correct?
2	Q. And I'm trying to understand what	2	A. That's correct. That's a
3	you've done on hernia repair and what you've done	3	statement. It has no diagnostic conclusion or
4	on transvaginal mesh, okay?	4	anything else.
5	A. Okay.	5	Q. Why did you include that language?
6	Q. And at this point, whether or not	6	A. As I said, it's a description of
7	the rate of nerve growth within transvaginal mesh	7	what we see, just for readers to understand what's
8	is less than the rate of nerve growth in the scar	8	going on under the microscope.
9	surrounding the mesh is an open hypothesis,	9	Q. There are clinicians who
10	correct?	10	contributed to this paper, right?
11	MR. ORENT: Objection.	11	A. Yes.
12	THE WITNESS: I can tell you that I	12	Q. Is it possible that to Dr. Bendavid
13	have some initial data, initial observations, but	13	or to Dr. Koch, that whether these were similar in
14	it's not completed. Statistics is not completed	14	size to ilioinguinal or iliohypogastric nerves had
15	yet.	15	some clinical bearing?
16	BY MS. BYARD:	16	MR. ORENT: Objection. Calls for
17	Q. Okay. Thank you, sir.	17	speculation.
18	Just to paraphrase, your findings with	18	THE WITNESS: Had no clinical bearing.
19	respect to hernia repair was that both scar tissue	19	BY MS. BYARD:
20	and scar tissue with mesh have a higher number of	20	Q. Did you write this sentence or did
21	nerves than virgin tissue, but that the difference	21	they?
22	between the two groups was not statistically	22	MR. ORENT: Objection.
23	significant? That's correct?	23	THE WITNESS: Oh, their manuscript was
24	A. (Witness nods.)	24	edited, rewritten several times, several people
25	Q. Now, if you look at the last	25	contributed.
	Page 123		Page 125
1	paragraph of the result section, which is just	1	I certainly contributed to each
2	before "discussion," you measured the nerves that	2	sentence in one way or another. And I measured.
3	you saw, right? And by that I mean, you measured	3	Nobody else could measure them.
4	their size?	4	BY MS. BYARD:
5	A. Diameter, yes.	5	Q. Are you the one who supplied the
6	Q. For your evaluation of	6	information about how the nerve sizes and diameter
7	transvaginal mesh specimens, you didn't measure the	7	compared to the size of known nerves in this
8	diameter of the nerves that you detected, did you?	8	particular anatomy?
9	A. No.	9	A. This is comparison of microscopic.
10	Q. Part of what you were doing here	10	So I contributed by microscopic what I see, and
11	in your study with Dr. Bendavid, was trying to	11	clinicians contributed to what they can see with
12	correlate the size of the diameter of the nerves	12	bare eyes without the microscope.
13	that you found to whether they were similar,	13	So the comparison is, roughly, for
14	dissimilar to inguinal or iliohypogastric nerves,	14	surgeons to understand that the nerves we are
15	correct?	15	talking about can be as big as those they can see
16	A. No.	16	by naked eye, but they can be much smaller that
17	Q. Tell me what you were trying to do	17	they cannot see them. Therefore, they cannot avoid
18	by measuring the diameter of the nerves then?	18	them.
		19	So basically it leads to readers to
19	A. What I've just described, so the		
20	readers would understand what I'm talking about.	20	understand that it's unavoidable to damage nerves
20 21	readers would understand what I'm talking about. Had no diagnostic significance.	20 21	because they are so small that surgeons cannot see
20 21 22	readers would understand what I'm talking about. Had no diagnostic significance. Q. Well, you write:	20 21 22	because they are so small that surgeons cannot see them.
20 21 22 23	readers would understand what I'm talking about. Had no diagnostic significance. Q. Well, you write: "At 0.9 millimeters, the size	20 21 22 23	because they are so small that surgeons cannot see them. Q. And it was important for the
20 21 22 23 24	readers would understand what I'm talking about. Had no diagnostic significance. Q. Well, you write: "At 0.9 millimeters, the size is not too dissimilar from that of	20 21 22 23 24	because they are so small that surgeons cannot see them. Q. And it was important for the surgeons to talk about the type of nerves that
20 21 22 23	readers would understand what I'm talking about. Had no diagnostic significance. Q. Well, you write: "At 0.9 millimeters, the size	20 21 22 23	because they are so small that surgeons cannot see them. Q. And it was important for the

	Page 126		Page 128
1	MR. ORENT: Objection.	1	" for a better understanding
2	THE WITNESS: I don't understand the	2	and application of anatomy, which
3	question. What do you mean, "type of nerves"?	3	easily transferred to tension free
4	BY MS. BYARD:	4	and laparoscopic repairs." Right?
5	Q. Well, it mentions specifically	5	A. That's correct.
6	inguinal and iliohypogastric nerves, doesn't it?	6	Q. He writes:
7	A. It's not a type of nerve. It's	7	"Today's leitmotif in hernia
8	just a name of a larger branch.	8	surgery, to accompany the newer
9	Q. Here, that name of those branches	9	techniques, has been the extensive
10	was important to specify?	10	use of prosthetic materials."
11	A. No.	11	A. That's correct. That's epidemics
12	Q. It was completely superfluous?	12	now.
13	MR. ORENT: Objection. Argumentative.	13	Q. He used he says:
14	THE WITNESS: This is something which	14	"The philosophy of tension free
15	surgeons have readily are familiar with. It's a	15	repair which was made possible by
16	comparison, it's like a sliding scale, from 1 to	16	the advent of synthetic materials
17	10. So everybody within the span would know what	17	was born in Marseille, France,
18	we're talking about.	18	fathered by Don Aqauviva in 1944,
19	BY MS. BYARD:	19	who used sagittate nylon sheets as
20	Q. You're not a pain specialist,	20	an onlay over a defect which itself
21	right?	21	was left intact."
22	A. What do you mean "pain	22	Did I read that correctly?
23	specialist"?	23	A. Yeah, you read it correctly.
24	Q. You don't treat and manage pelvic	24	Q. He says:
25	pain, do you?	25	"The theme was re-visited by
	F		
	Page 127		Page 129
1	Page 127 A. That's correct.	1	Page 129 Henri Fruchaud in 1956, who designed
1 2		1 2	
	A. That's correct.Q. And you're not a neurologist?A. No, I am not a neurologist. You	1	Henri Fruchaud in 1956, who designed
2	A. That's correct.Q. And you're not a neurologist?	2	Henri Fruchaud in 1956, who designed an operation also using nylon mesh
2 3	A. That's correct.Q. And you're not a neurologist?A. No, I am not a neurologist. You	2 3	Henri Fruchaud in 1956, who designed an operation also using nylon mesh in a manner which was antedated and
2 3 4	A. That's correct.Q. And you're not a neurologist?A. No, I am not a neurologist. You know what I am, I am pathologist.	2 3 4	Henri Fruchaud in 1956, who designed an operation also using nylon mesh in a manner which was antedated and precisely anticipated Francis Usher."
2 3 4 5	 A. That's correct. Q. And you're not a neurologist? A. No, I am not a neurologist. You know what I am, I am pathologist. Q. And you're not a specialist in 	2 3 4 5	Henri Fruchaud in 1956, who designed an operation also using nylon mesh in a manner which was antedated and precisely anticipated Francis Usher." Did I read that correctly?
2 3 4 5 6	A. That's correct. Q. And you're not a neurologist? A. No, I am not a neurologist. You know what I am, I am pathologist. Q. And you're not a specialist in sexual health, correct?	2 3 4 5 6	Henri Fruchaud in 1956, who designed an operation also using nylon mesh in a manner which was antedated and precisely anticipated Francis Usher." Did I read that correctly? A. Yes, it appears you read it
2 3 4 5 6 7	A. That's correct. Q. And you're not a neurologist? A. No, I am not a neurologist. You know what I am, I am pathologist. Q. And you're not a specialist in sexual health, correct? A. I just answered, I'm a	2 3 4 5 6 7	Henri Fruchaud in 1956, who designed an operation also using nylon mesh in a manner which was antedated and precisely anticipated Francis Usher." Did I read that correctly? A. Yes, it appears you read it correctly.
2 3 4 5 6 7 8	A. That's correct. Q. And you're not a neurologist? A. No, I am not a neurologist. You know what I am, I am pathologist. Q. And you're not a specialist in sexual health, correct? A. I just answered, I'm a pathologist.	2 3 4 5 6 7 8	Henri Fruchaud in 1956, who designed an operation also using nylon mesh in a manner which was antedated and precisely anticipated Francis Usher." Did I read that correctly? A. Yes, it appears you read it correctly. Q. "Usher provided the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. That's correct. Q. And you're not a neurologist? A. No, I am not a neurologist. You know what I am, I am pathologist. Q. And you're not a specialist in sexual health, correct? A. I just answered, I'm a pathologist. Q. Let's look at the discussion, please. You describe here that: "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance." A. Yes, that was mostly Dr. Bendavid's contribution in this part. Q. I like his writing style. A. English is not my first language, so he writes better than me. Q. He writes:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Henri Fruchaud in 1956, who designed an operation also using nylon mesh in a manner which was antedated and precisely anticipated Francis Usher." Did I read that correctly? A. Yes, it appears you read it correctly. Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique." Did I read that correctly? A. That's correct. Q. And then it continues that in this next full paragraph: "While several surgical techniques based on the principles of tension free repairs have been introduced in the last 30 years, polypropylene has become the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. That's correct. Q. And you're not a neurologist? A. No, I am not a neurologist. You know what I am, I am pathologist. Q. And you're not a specialist in sexual health, correct? A. I just answered, I'm a pathologist. Q. Let's look at the discussion, please. You describe here that: "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance." A. Yes, that was mostly Dr. Bendavid's contribution in this part. Q. I like his writing style. A. English is not my first language, so he writes better than me. Q. He writes: "A mini-revival took place with the rediscovery of"	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Henri Fruchaud in 1956, who designed an operation also using nylon mesh in a manner which was antedated and precisely anticipated Francis Usher." Did I read that correctly? A. Yes, it appears you read it correctly. Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique." Did I read that correctly? A. That's correct. Q. And then it continues that in this next full paragraph: "While several surgical techniques based on the principles of tension free repairs have been introduced in the last 30 years, polypropylene has become the dominant olefin utilized to that end." Did I read that correctly?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. That's correct. Q. And you're not a neurologist? A. No, I am not a neurologist. You know what I am, I am pathologist. Q. And you're not a specialist in sexual health, correct? A. I just answered, I'm a pathologist. Q. Let's look at the discussion, please. You describe here that: "Indolent years of barber surgeons and anatomists and the beginning of a surgical renaissance." A. Yes, that was mostly Dr. Bendavid's contribution in this part. Q. I like his writing style. A. English is not my first language, so he writes better than me. Q. He writes: "A mini-revival took place with the rediscovery of" And then he names some researchers and surgeons, right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Henri Fruchaud in 1956, who designed an operation also using nylon mesh in a manner which was antedated and precisely anticipated Francis Usher." Did I read that correctly? A. Yes, it appears you read it correctly. Q. "Usher provided the polyethylene, then polypropylene while reproducing Fruchaud's technique." Did I read that correctly? A. That's correct. Q. And then it continues that in this next full paragraph: "While several surgical techniques based on the principles of tension free repairs have been introduced in the last 30 years, polypropylene has become the dominant olefin utilized to that end." Did I read that correctly? A. That's correct.

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1 2 3 4 5 6 7 8 9 10 11	A. Yes. Q. And a synthetic polymer discovered by J. Paul Hogan and Robert Banks of the Phillips Petroleum Company; do you see that? A. I lost you. Yes, I do see that. Q. And it says: "This discovery was made	1 2 3 4	effect on tissue components." That's what's written here in your article, right?
3 4 5 6 7 8 9 10	by J. Paul Hogan and Robert Banks of the Phillips Petroleum Company; do you see that? A. I lost you. Yes, I do see that. Q. And it says:	3	That's what's written here in your
4 5 6 7 8 9 10	by J. Paul Hogan and Robert Banks of the Phillips Petroleum Company; do you see that? A. I lost you. Yes, I do see that. Q. And it says:	1	
5 6 7 8 9 10	Petroleum Company; do you see that? A. I lost you. Yes, I do see that. Q. And it says:	4	
6 7 8 9 10	A. I lost you. Yes, I do see that.Q. And it says:		A. That's correct.
7 8 9 10 11	Q. And it says:	5	Q. In this sentence you don't write
7 8 9 10 11		6	that "tissue forces and chemical environment affect
8 9 10 11	I his discovery was made	7	the mesh, which in turn has an effect on tissue
9 10 11	possible, thanks to the pioneering	8	components," do you?
10 11	work and olefin chemistry by two	9	A. I have to see the sentence.
11	Nobel Prize laureates 1963, Giulio	10	MR. ORENT: Where is the sentence
	Natta and Karl Ziegler."	11	you're looking at, at this point?
12	Do you see that?	12	MS. BYARD: It's the first sentence
13	MR. ORENT: Objection.	13	preceding the discussion of Figure A and Figure B.
14	THE WITNESS: That's correct.	14	THE WITNESS: Oh, this is like a
15	BY MS. BYARD:	15	
		l .	feedback, this is a description. See, first is
16	Q. And then it goes on to describe	16	description that mesh affects, and then there is
17	there being an "unexpected and unpredicted	17	effect. And then there is a tissue which is
18	prominence of pain" being the most common	18	affecting mesh, and but mesh can react back, so
19	complication seen in mesh groin hernia repairs	19	it's a complex sort of mechanism, which he has not
20	today, doesn't it?	20	studied yet.
21	A. That's correct.	21	BY MS. BYARD:
22	Q. There's a discussion then about	22	Q. And the stage that you're at here
23	the industry development of lighter mesh, meshes	23	with hernia mesh, is understanding the tissue
24	with larger pores. Do you see that?	24	response to mesh, right?
25	A. Yes.	25	MR. ORENT: Objection.
1	Q. And it essentially then describes	1	THE WITNESS: It's hard to actually
2	this, this tradeoff in terms of collagen versus	2	differentiate what is mesh response to tissue, or
3	scar tissue ingrowth?	3	tissue response to mesh, or what is mesh effect on
	A. You would have to read the	4	the tissue, or what is tissue reaction to the mesh.
4		5	I mean, it's interaction between mesh and tissue.
5	sentence to me.	6	
6	Q. Sure. I just, I would hope to	1	But the intricate details of how this
7	summarize. Essentially here, and correct me if I	7	feeds back and catalyzes the process, I have not
8	don't get this accurately, but essentially here you	8	studied. Molecular mechanisms.
9	go on then to describe there being tradeoffs	9	BY MS. BYARD:
10	between wider pore lighter, larger pore meshes	10	Q. And the same is true for
11	and smaller pore heavier weight meshes, correct?	11	transvaginal mesh, true?
12	MR. ORENT: Objection.	12	MR. ORENT: Objection.
13	THE WITNESS: Yeah, we discussed that	13	THE WITNESS: That's correct. We can
14	topic.	14	see the changes, what is the end result. But how
15	BY MS. BYARD:	15	this is all happening, and through what molecules,
16	Q. Sure. And then it says:	16	and this is not studied yet.
17	"To understand the complex	17	BY MS. BYARD:
18	interaction between the olefins and	18	Q. If you turn to page 808, please.
19	biological tissues, their site of	19	A. Yes.
20	contact needs to be studied as a	20	Q. There is a discussion of you all
21	compartmentalized living tissue."	21	setting up a mesh retrieval industry; do you see
22	A. That's correct.	22	that?
23	Q. "Additionally, tissue forces	23	A. Yes.
24	and chemical environments affect the	24	Q. And there being a protocol
25	mesh which in turn may have an	25	developed to address how contributions are made to

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Page 134 Page 136 1 the registry? 1 after I examine the specimens, then they are all 2 A. Not exactly. Not how 2 put in all table, and then I can see the 3 contributions are made. Dr. Bendavid through his 3 difference. But final statistical analysis is done 4 4 contacts with colleagues, I mean, we started by Dr. Lou, she does statistical tests. 5 acquiring meshes just to build a library of 5 Q. So she's inputting the reasons for 6 specimens and examine them. 6 the excision, the clinical presentation, severity 7 O. And then it says: 7 of the pain, she's inputting that with your 8 "The next step will be the 8 histological findings? 9 correlation of histology/pathology 9 MR. ORENT: Objection. 10 to the clinical presentation and 10 THE WITNESS: No. I'm receiving the 11 severity of pain." 11 specimens, I'm receiving initial information with A. Yes, that's correct. 12 12 the specimens. 13 Q. What will your role be in this 13 BY MS. BYARD: 14 registry as far as you understand it? 14 Q. What initial information? 15 A. Not will be, I'm collecting 15 A. Reason for excision. I'm 16 specimens, I'm examining them. 16 collecting age, gender, heterology, type of hernia, 17 Q. Is your job to do the correlation 17 is it ventral, is it molecular, is it inguinal, I'm 18 of the histology pathology to the clinical 18 collecting all this clinical information with the 19 presentation and severity of pain? 19 specimen. It comes with specimens. 20 A. Yes. I mean, I examine these 20 Q. You conclude this paragraph by 21 specimens, There is history in them. Statistician 21 writing: 22 is involved, so she's Dr. Lou is doing final 22 "This is the duty of our 23 statistical analysis. So statistical tests are 23 profession. It is an oath" -- I'm 24 applied by her. I do some statistics as well on 24 sorry. I didn't start soon enough. Let me strike all that. 25 the go and... 25 Page 135 Page 137 1 Q. Who's the one evaluating the You write: 2 clinical presentation severity of pain for this 2 "While knowledge comes, let us 3 registry, though? 3 translate it into wise application 4 A. Mostly treating clinicians, so 4 for which it was meant. This is the 5 they provide -- I mean, at this stage what we duty of our profession, it is an 6 manage to do is separate specimens according to 6 oath which we must honor proudly, 7 7 reason for excision. disconnected from any notions of 8 8 personal or commercial conflicts of So if pain is severe enough to cause 9 excision without any other factors, or if pain was 9 interest." 10 contributing factor as a reason for excision, 10 Do you agree with those statements? 11 assuming there is a combination of pain and hernia 11 THE WITNESS: Yes, I do. 12 reoccurrence. Or, when the pain either didn't 12 BY MS. BYARD: 13 exist, or pain was low enough not to trigger 13 Q. Here in the conclusion, and we had 14 incision, but mesh was either excised or sampled 14 started to talk about this in the abstract, and so 15 during revision of hernia reoccurrence. So that's 15 I wanted to return to it because you had pointed me 16 where we ended up. I mean, so severity of pain 16 that further on in the paper there would be 17 became assessed as a reason for excision. 17 discussion of it. So let's look at that. Q. Okay. And that's done by the 18 18 You write in the conclusion: treating physician, correct? 19 19 "It is felt that the mechanism 20 A. Yes. 20 of pain associated with the use of 21 21 mesh may similarly be due to micro Q. And then the correlation between 22 the pathology, what you find under microscopic 22 entrapment and micro compartment 23 examination, and this clinical presentation, 23 types of syndromes through new nerve 24 severity of pain, who does that job? 24 and vessel ingrowth within the mesh 25 25 A. Initially, I see it. I mean, pores and other confining spaces

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	Page 138		Page 140
1	with the concomitant edema, anoxia,	1	findings are there.
2	thrombi scarring, distortion,	2	The balance of them, the details and
3	migration and traction."	3	everything else, again, is not studied, it needs to
4	THE WITNESS: That is correct.	4	be further studied. But the findings, the
5	BY MS. BYARD:	5	abnormality is visibile, it's there. It's
6	Q. Do you see that?	6	100 percent there.
7	A. That's correct.	7	Q. So the you have observed and
8	Q. And is that what you were	8	established tissue abnormalities with hernia mesh,
9	referring me back to when we were talking about the	9	right?
10	abstract?	10	A. Yes.
11	A. Yes.	11	Q. The step that hasn't been done yet
12	Q. Again, you say that:	12	is understanding the mechanism by which those
13	"It is felt that the mechanism	13	tissue abnormalities lead to clinical complications
14	of pain associated with the use of	14	of pain?
15	mesh may be due to micro entrapment	15	A. Yes. Details of those mechanisms.
16	and micro compartment." Right?	16	Q. And with respect to transvaginal
17	A. It says "similarly."	17	mesh, you're one step behind the study in that you
18	Q. So the analogy that you're making	18	haven't yet done the statistical analysis of
19	A. So the mechanism is similarly.	19	relative rates of nerve ingrowth and
20	Not that it's due or not due. The "may" implies a	20	compartmentalization?
21	similarity.	21	MR. ORENT: Objection.
22	Q. Between what and what?	22	THE WITNESS: What do you mean, one
23	A. Yes.	23	step behind or in front?
24	Q. Between what and what?	24	BY MS. BYARD:
25	A. Between compartment syndromes we	25	Q. Well, this study, this statistical
	Page 139		Page 141
1	already know, and these new compartment syndromes	1	analysis has been done. That statistical analysis
2	we just discovered.	2	is yet to be done for transvaginal mesh?
3	Q. So the mechanism of pain is	3	MR. ORENT: Objection.
4	understood for compartment syndromes that are	4	THE WITNESS: Are you asking in respect
5	already established?	5	of my opinions, or in respect of research and plans
6	A. Yes.	6	for research?
7	Q. And the mechanism of pain	7	BY MS. BYARD:
8	associated with mesh may be similar for compartment	8	Q. I'm talking about the body of
9	syndromes that you're beginning to study here?	9	scientific knowledge that's available. This was a
10	A. Yeah. Mechanisms may not be	10	contribution to the understanding of the tissue
11	exactly the same, but may be similar. Likely to be	11	response to
12	similar.	12	A. Yes, I understand that.
13	Q. Because at this point in the study	13	Q to hernia repair?
14	of hernia repair, those mechanisms of pain are not	14	A. Are you asking if this analysis
15	established yet?	15	was done to derive to the conclusions of this
16	MR. ORENT: Objection.	16	report, or are we talking just hypotheticals
17	BY MS. BYARD:	17	scientific questions.
17 18	BY MS. BYARD: Q. Right?	17 18	scientific questions. MR. ORENT: Perhaps you can rephrase
17 18 19	BY MS. BYARD: Q. Right? A. Details of the mechanisms. So	17 18 19	scientific questions. MR. ORENT: Perhaps you can rephrase the question.
17 18	BY MS. BYARD: Q. Right?	17 18	scientific questions. MR. ORENT: Perhaps you can rephrase the question. BY MS. BYARD:
17 18 19	BY MS. BYARD: Q. Right? A. Details of the mechanisms. So	17 18 19	scientific questions. MR. ORENT: Perhaps you can rephrase the question.
17 18 19 20	BY MS. BYARD: Q. Right? A. Details of the mechanisms. So when we observe the changes in the mesh, we clearly saw that the scar tissue within the mesh is not normal scar tissue.	17 18 19 20	scientific questions. MR. ORENT: Perhaps you can rephrase the question. BY MS. BYARD:
17 18 19 20 21	BY MS. BYARD: Q. Right? A. Details of the mechanisms. So when we observe the changes in the mesh, we clearly saw that the scar tissue within the mesh is not	17 18 19 20 21	scientific questions. MR. ORENT: Perhaps you can rephrase the question. BY MS. BYARD: Q. Okay. Let me try and do that.
17 18 19 20 21 22	BY MS. BYARD: Q. Right? A. Details of the mechanisms. So when we observe the changes in the mesh, we clearly saw that the scar tissue within the mesh is not normal scar tissue.	17 18 19 20 21 22	scientific questions. MR. ORENT: Perhaps you can rephrase the question. BY MS. BYARD: Q. Okay. Let me try and do that. And I only am trying to say that with

36 (Pages 138 to 141)

	Page 142		Page 144
1	transvaginal meshes.	1	Exhibit 1196?
2	Q. You've identified tissue abnormalities?	2	A. It's not scientific rigor or
3	A. Even more. I found more in	3	scientific work. This is diagnostic work; this is
4	transvaginal meshes than in what is the hernia	4	scientific work. This is research; this is
5	meshes.	5	diagnostic. When I see abnormal, I state. Here is
6	Q. Okay.	6	a specific question.
7	A. So in this respect, this part is	7	I mean, you're just trying to mix
8	step ahead from this.	8	things which are not not the same.
9	Q. Well, in terms of the degree of	9	Q. But you've made conclusions in
10	abnormalities, you're saying?	10	your report on transvaginal mesh that are broader
11	MR. ORENT: Objection.	11	than the conclusions that you've reached in this
12	THE WITNESS: Yes.	12	study?
13	BY MS. BYARD:	13	A. Yes.
14	Q. Okay.	14	MR. ORENT: Objection.
15	A. There are way more findings in	15	BY MS. BYARD:
16	transvaginal meshes than in hernia meshes. This	16	Q. Right?
17	study was specifically focused on nerve ingrowth.	17	MR. ORENT: Point out a particular
18	What we found there, abnormality in the scar tissue	18	question if you have one.
19	was observation only, sort of, on the way we did	19	THE WITNESS: This part okay.
20	the study.	20	BY MS. BYARD:
21	This was done later, and there are more	21	Q. Go ahead.
22	findings, more abnormalities in transvaginal	22	A. No.
23	meshes.	23	MR. ORENT: Wait for a proper question.
24	Q. You've gotten to the level,	24	MS. BYARD: Are you instructing him not
25	though, of doing a statistical analysis to quantify	25	to answer that question?
	Page 143		Page 145
1	the tissue abnormalities for hernia mesh?	1	MR. ORENT: No. I think there's no
2	A. Yes.	2	question pending that's intelligible.
3	Q. And you haven't reached that stage	3	All you said is, "there are some
4	yet for transvaginal mesh?	4	opinions in here that are broader than those." But
5	MR. ORENT: Objection.	5	you haven't identified any opinions for him to
6	THE WITNESS: Well, it's present.	6	address specifically.
7	Whatever is present here is 100 percent. I see	7	BY MS. BYARD:
8	abnormality, it's stated there.	8	Q. Do you agree with what I've said, sir?
9	These rate and frequencies and	9	MR. ORENT: Objection.
10	everything else, only makes sense for scientific	10	THE WITNESS: Opinions or I'm a
11	questions.	11	little bit confused. I mean
12	But for detection of abnormality in the	12	BY MS. BYARD:
13	specific specimen or specific patient, is	13	Q. Okay. That's okay, I can rephrase it.
14	100 percent. I see it or I don't see it. If I	14	So here in your study with Dr. Bendavid
15	don't see it, I don't describe it.	15	on hernia mesh, you've described what the
16	BY MS. BYARD:	16	mechanisms of pain may be for the relationship
17	Q. Okay.	17	between tissue abnormalities and clinical
18	A. We are talking about this specific	18	complications, right?
19	reports which are produced for each specific	19	MR. ORENT: Objection.
20	patient, and this was done for actually one	20	THE WITNESS: Details of this
21		21	mechanisms, the connection. I mean, I see so,
	specific scientific question.	22	we know that there is reason for excision, we know
22	Q. And I guess I'm operating off the assumption that you've applied the same level of	23	that there are pathological findings. What we see
22		. 43	mat mere are pamological illidings. What we see
23			
23 24 25	scientific rigor, that you did in this publication that you did with Dr. Bendavid, that you did for	24 25	in the microscope is not normal, it's abnormal. We know that the mesh caused clinical

Page 146 Page 148 1 1 symptom, had to be excised. How this all happened innervation of the tissue, the tissue would not 2 in small details, up to very small molecules of how 2 sense any pain. So this is, this is predictable. 3 they interact, is not known. 3 If we have inflammation, we know that 4 4 But we know the effect, and we know the there will be lower threshold for pain. This has 5 5 pathological findings behind it. But the details been studied extensively in other areas of 6 6 of this connection, these small sort of details are inflammation. Inflammation is always associated 7 7 not clear. with lower threshold of pain. What doesn't hurt in 8 Some of it is, as mentioned, are 8 normal tissue, may hurt in inflamed tissue. 9 similar to more study there is, like toothache I 9 So inflammation is high enough, it will 10 10 said, or heart attack. But again, this is in cause pain on its own. Inflammation itself will be 11 11 enough to cause pain, but it may not be enough, and pieces. 12 12 BY MS. BYARD: then it will need the extra stimulus such as edema. 13 13 Q. So, for instance, you could have a This is very complex interaction. 14 nerve that was grown into scar tissue, that doesn't 14 BY MS. BYARD: 15 15 cause so much pain that the scar tissue has to be Q. And so -- but those specific 16 excised, right? 16 mechanisms of how this relationship between nerve 17 MR. ORENT: Objection. 17 ingrowth or vascular ingrowth, scar tissue, THE WITNESS: This can happen. I mean, 18 18 inflammation, and whether or not that will cause or 19 it may or may not. People are different. 19 predict pain in a patient is not yet described? 20 BY MS. BYARD: 20 MR. ORENT: Objection. 21 THE WITNESS: It is described in other 21 Q. And so you can look at a slide of 22 mesh, with scar tissue, and see a nerve grown into 22 areas. It's a general knowledge of what they 23 23 it, and you can't predict whether that patient had accumulated. I mean, does inflamed knee hurt? I 24 24 mean, what do you think? It's not just described, pain, can you? 25 it is a general knowledge. Something is inflamed, 25 A. I can say that there is Page 147 Page 149 probability, there is mechanism for pain in that 1 it may hurt. 1 BY MS. BYARD: 2 2 specific, if patient have or didn't have pain, this 3 may depend on different circumstances. It may not 3 Q. Do you know whether 100 percent of 4 hurt today, but it has probability it may hurt 4 patients with edema present in their mesh and the 5 5 tomorrow. tissues surrounding their mesh will feel pain? 6 6 A. What's percentage of those who So this would be, again, complex. And 7 7 it's not just for a nerve. If there is a nerve have edema or don't have edema? I don't know exact 8 ingrown in the tissue, it means that the tissue is 8 percentage. And I don't think it matters, because 9 alive. It can sense pain. So this is the 9 it might be multiple mechanisms. 10 baseline. Then, pain can occur at any time there. 10 So their pathological findings which You add extra stimuli for pain, damage to the are normal, and the degree of their contribution to 11 11 12 12 tissue, inflammation, edema -- the more you add, pain development is hard to predict because it's so 13 the probability goes higher and higher. But, 13 complex. 14 14 again, you may have just a nerve ingrowth and it Q. And not yet known? 15 gets tugged, and you have mechanism of pain right 15 MR. ORENT: Objection. 16 away. So this is so complex, and a variable 16 THE WITNESS: What do you mean, "not 17 between people, we cannot apply a specific --17 yet known?" We know that inflamed tissue hurts. 18 BY MS. BYARD: 18 now I'm --19 19 Q. It's not predictable? Q. But the rates at which it will 20 MR. ORENT: Objection. 20 occur -- for instance, with edema, you can't tell THE WITNESS: No, this is not true. 21 21 me the rates at which pain will occur or --22 It's predictable. If you have nerve ingrowth, you 22 A. The main question is, it can 23 have baseline for pain development. 23 happen. If it happens in the patient, you know why 24 So, once you have innervation of the 24 this is happening. Assuming, if an area in the 25 25 tissue, pain can develop. If you don't have body hurts, and you take a biopsy, and you see

	Page 150		Page 152
1	inflammation in there, but you don't see anything	1	many points of contact with other agencies, not
2	else, what would be your logical conclusion, why	2	everything is disclosed, or authors decide for that
3	did it hurt? Because it was inflamed and you don't	3	specific study there is no conflict of interest.
4	see anything else.	4	It's more up to the discretion of the author.
5	The same with meshes. Meshes hurt;	5	Q. But all things being equal, the
6	they come out. There is no tumor in it, there is	6	better course would be if the bias might affect the
7	no informal carcinoma, but there is nerve ingrowth,	7	subject of study, to disclose that conflict of
8	there is mesh, there is scarring.	8	interest, right?
9	Therefore, the only reason for it to	9	A. Yes
10	hurt is mesh-related changes. But the degree of	10	MR. ORENT: Objection.
11	contribution of how much inflammation contributed,	11	THE WITNESS: it's the best sort of
12	how much edema contributed, is difficult to	12	scientific practice. Not practice, but
13	predict. It has been studied in other areas. It	13	BY MS. BYARD:
14	was not studied in specific details in meshes.	14	Q. It's important for authors in the
15	Q. Thank you.	15	scientific and medical community, to disclose
16	Let me check the time.	16	conflict of interest?
17	MS. BYARD: Do you guys have steam for	17	MR. ORENT: Objection.
18	another article before we break for lunch?	18	THE WITNESS: It's important for
19	THE WITNESS: I have to go to the	19	readers to know if there's potential conflict of
20	washroom.	20	interest, yes.
21	MR. ORENT: Why don't we take five.	21	BY MS. BYARD:
22	THE VIDEOGRAPHER: Off the record at	22	
23		23	Q. So, at this point, you have been
	12:24 p.m.	24	deposed, I think we had the number at around seven
24	RECESS AT 12:24		or eight times in litigation where you've testified
25	UPON RESUMING AT 12:40	25	as an expert against mesh manufacturers, right?
	Page 151		Page 153
1	THE VIDEOGRAPHER: We're back on the	1	A. That's correct.
2	record at 12:40 p.m.	2	Q. And you've never once testified
3	BY MS. BYARD:	3	for a defendant manufacturer in a medical device
4	Q. Doctor, would you agree with me	4	case, correct?
5	that it's important to keep bias out of scientific		
6		5	A. You mean like crossing sides? No.
	research?	5	A. You mean like crossing sides? No.O. You never testified on behalf of a
7		6	Q. You never testified on behalf of a
	MR. ORENT: Objection.	6 7	Q. You never testified on behalf of a mesh manufacturer in that company's defence?
7 8	MR. ORENT: Objection. THE WITNESS: Yes. Yes, it is	6 7 8	Q. You never testified on behalf of a mesh manufacturer in that company's defence? MR. ORENT: Objection.
7 8 9	MR. ORENT: Objection. THE WITNESS: Yes. Yes, it is important.	6 7 8 9	Q. You never testified on behalf of a mesh manufacturer in that company's defence? MR. ORENT: Objection. THE WITNESS: No.
7 8 9 10	MR. ORENT: Objection. THE WITNESS: Yes. Yes, it is important. BY MS. BYARD:	6 7 8 9 10	Q. You never testified on behalf of a mesh manufacturer in that company's defence? MR. ORENT: Objection. THE WITNESS: No. BY MS. BYARD:
7 8 9 10 11	MR. ORENT: Objection. THE WITNESS: Yes. Yes, it is important. BY MS. BYARD: Q. And you would agree that bias in	6 7 8 9 10 11	Q. You never testified on behalf of a mesh manufacturer in that company's defence? MR. ORENT: Objection. THE WITNESS: No. BY MS. BYARD: Q. And since 2012, early 2013, all of
7 8 9 10 11 12	MR. ORENT: Objection. THE WITNESS: Yes. Yes, it is important. BY MS. BYARD: Q. And you would agree that bias in the form of industry influence, is bad for science,	6 7 8 9 10 11 12	Q. You never testified on behalf of a mesh manufacturer in that company's defence? MR. ORENT: Objection. THE WITNESS: No. BY MS. BYARD: Q. And since 2012, early 2013, all of the work that you've done on mesh as an expert in
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	Page 154		Page 156
1	BY MS. BYARD:	1	A. Payment is not the only bias, I
2	Q. You're paid by plaintiffs for your	2	will mean only other bias. I mean it's just what
3	time?	3	you consider. But people may be biased by
4	MR. ORENT: Objection.	4	something else.
5	THE WITNESS: Sometimes, like today, I	5	EXHIBIT NO. 1198: International
6	don't know, maybe you will pay for that, I mean	6	Scholarly and Scientific Research &
7	I actually sometimes don't know where the money	7	Innovation, 2014, Publication entitled,
8	comes from. There's so many people involved.	8	"Pathology of Explanted Transvaginal
9	BY MS. BYARD:	9	Meshes," by Dr. V. Iakovlev,
10	Q. And while there's nothing I	10	Dr. E. T. Carey and Dr. J. Steege.
11	guess returning to my question about disclosures.	11	BY MS. BYARD:
12	There's nothing that prevents an author from	12	Q. Doctor, do you recognize
13	providing disclosures of conflicts of interest if	13	Exhibit 1198?
14	the author feels that's important, right?	14	A. Yes, it's a paper I co-authored.
15	A. For full articles, it's usually a	15	Q. Dr. Erin Teeter Carey is an expert
16	requirement, but sometimes for abstracts, I mean,	16	whose time is paid for by the Plaintiffs in the
17	then you don't know where to squeeze it, if there	17	mesh litigation; isn't she?
18	is no line when you submit it. So for abstracts	18	A. Yes.
19	there may be no space to put this disclosure.	19	Q. And Dr. John Steege is a paid
20	So if I don't have that space, while	20	Plaintiffs' expert too, right?
21	submitting an abstract, I insert a slide disclosing	21	A. Yes.
22	that I've been consulting for medical-legal cases.	22	Q. And you were in fact introduced to
23	I don't remember single time when I never when I	23	Dr. Erin Teeter Carey and Dr. John Steege by
24	have not disclosed it.	24	Margaret Thomson, a lawyer for the Plaintiffs,
25	Either way, I will find a way how to	25	right?
	Page 155		Page 157
1	disclose it. Either during presentation or during	1	A. Yeah. I think first contact was
2	abstract submission, or any other way.	2	during a conference call, and I think Dr. Thomson
3	Q. Were all the publications that you	3	was either participant or organizer of that call.
4	have authored on transvaginal mesh published in	4	Q. She was acting as a lawyer during
5	2014?	5	that conference call, correct?
6	A. Yes.	6	MR. ORENT: Objection. At this point,
7	Q. And the articles that you've	7	I'm going to instruct the witness not to answer to
8	authored on transvaginal mesh have direct bearing	8	the extent that there are that this was as part
9	on the reasons for your opinions in the lawsuit,	9	of a case consultation or work.
10	right?	10	You can answer to the extent that you
11	MR. ORENT: Objection to form.	11	had any conversations with the four of those people
12	THE WITNESS: It's kind of I	12	related to non-litigation work.
13	wouldn't word it like this. I considered all the	13	BY MS. BYARD:
14	knowledge extracted during, doing this research	14	Q. Dr. Margaret Thomson was on the
15	project in formulating my opinions in these	15	call in her capacity as a lawyer, not in her
16	reports, yes.	16	capacity as a medical doctor, right?
17	BY MS. BYARD:	17	MR. ORENT: Objection.
18	Q. Well, and in fact, in all of the	18	THE WITNESS: I don't know. She's a
19	publications that you authored, that came out this	19	doctor and a lawyer, I mean, what capacity she's
20	year, you included information that you identified	20	serving in
	during your work as a paid expert for the	21	BY MS. BYARD:
21		1 00	Q. You were paid for your time on
22	Plaintiffs, correct?	22	
22 23	A. Yes. As I said, I mean, I	23	these conference calls by Plaintiffs' lawyers or
22			

	Page 158		Page 160
1	THE WITNESS: I don't think I	1	significance? I didn't hear you.
2	specifically charged for all these conference calls	2	A. The degree of statistical
3	or contacts. It depends, I mean, it's	3	significance is not either assessed, or is not
4	BY MS. BYARD:	4	95 percent, or there are other factors which
5	Q. You weren't there in conjunction	5	introduce the degree of unknown factors.
6	with your work as an anatomical pathologist at	6	Q. Okay. So here, for whether or not
7	St. Michael's, though, right?	7	the pathological examination explains mechanisms of
8	MR. ORENT: I'm going to now instruct	8	complications resulting in product excision, which
9	the witness this is all covered by Rule 26	9	one of those factual scenarios that you described
10	privileges. So if you want to ask questions	10	applied? Is that, is it that there was not an
11	related to his work on these papers, I'll let him	11	assessment of statistical significance? Was it
12	answer anything related to the papers. But if	12	that there was other confounding factors, or that
13	you're asking about his specific relationship with	13	the degree of significance was not statistically
14	Plaintiffs, Plaintiffs' experts and trial strategy	14	the degree of difference was not statistically
15	meetings, I'm going to specifically instruct him	15	significant?
16	not to answer.	16	MR. ORENT: Objection.
17	BY MS. BYARD:	17	THE WITNESS: No, neither. Because
18	Q. Are you going to follow Counsel's	18	this states a hypothesis, so before we started, we
19	instruction?	19	examined and we had a hypothesis made. So it was
20	A. As I said initially, I had first	20	this statement describes state of the research
21	contact	21	project before the research project.
22	MR. ORENT: I only want you to answer	22	BY MS. BYARD:
23	as to the extent that you can answer without	23	Q. Okay. So let's look at the
24	revealing any trial strategy meetings you may have	24	discussion on page 508. The last paragraph of the
25	attended, or anything related to your consultation	25	discussion on page 308. The last paragraph of the discussion ends after discussion of nerve
23	attended, or anything related to your consultation	23	discussion ends after discussion of herve
	Page 159		Page 161
1	Page 159 related to Plaintiffs in this litigation.	1	Page 161 entrapment and compression, stretching, edema,
1 2		1 2	
	related to Plaintiffs in this litigation.		entrapment and compression, stretching, edema,
2	related to Plaintiffs in this litigation. THE WITNESS: Okay.	2	entrapment and compression, stretching, edema, ischemia.
2	related to Plaintiffs in this litigation. THE WITNESS: Okay. BY MS. BYARD:	2 3	entrapment and compression, stretching, edema, ischemia. It says: "The roles of these
2 3 4	related to Plaintiffs in this litigation. THE WITNESS: Okay. BY MS. BYARD: Q. Let's take a look at the abstract	2 3 4	entrapment and compression, stretching, edema, ischemia. It says: "The roles of these mechanisms need to be further studied," doesn't it?
2 3 4 5	related to Plaintiffs in this litigation. THE WITNESS: Okay. BY MS. BYARD: Q. Let's take a look at the abstract of this published article conceived in a conference	2 3 4 5	entrapment and compression, stretching, edema, ischemia. It says: "The roles of these mechanisms need to be further studied," doesn't it? A. Yes. Exactly which part of can
2 3 4 5 6	related to Plaintiffs in this litigation. THE WITNESS: Okay. BY MS. BYARD: Q. Let's take a look at the abstract of this published article conceived in a conference call with Plaintiffs' counsel.	2 3 4 5 6	entrapment and compression, stretching, edema, ischemia. It says: "The roles of these mechanisms need to be further studied," doesn't it? A. Yes. Exactly which part of can you point? Q. Yes, yes. Excuse me. The last
2 3 4 5 6 7	related to Plaintiffs in this litigation. THE WITNESS: Okay. BY MS. BYARD: Q. Let's take a look at the abstract of this published article conceived in a conference call with Plaintiffs' counsel. MR. ORENT: And I'm going move to	2 3 4 5 6 7	entrapment and compression, stretching, edema, ischemia. It says: "The roles of these mechanisms need to be further studied," doesn't it? A. Yes. Exactly which part of can you point?
2 3 4 5 6 7 8	related to Plaintiffs in this litigation. THE WITNESS: Okay. BY MS. BYARD: Q. Let's take a look at the abstract of this published article conceived in a conference call with Plaintiffs' counsel. MR. ORENT: And I'm going move to strike that comment as without foundation.	2 3 4 5 6 7 8	entrapment and compression, stretching, edema, ischemia. It says: "The roles of these mechanisms need to be further studied," doesn't it? A. Yes. Exactly which part of can you point? Q. Yes, yes. Excuse me. The last sentence of the first full paragraph under
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their composition and effect on the tissue."	1 2	ingrowth, then degradation itself, how much of one
tissue."	۱ ၁	
		of those contribute and so on. It's, again, degree
Did I read that correctly?	3	of uncertainty.
A. That is correct.	4	Also, degradation is continuous
Q. And then in the last sentence of	5	process, so it will build up over the years, in the
the last paragraph of the discussion, it says:	6	beginning so there's a degree of uncertainty
"We believe that these	7	between all of those. I mean, what we know, it
specimens contain information of the	8	degrades, and with what we know, it hardens. So
mechanisms of complications and	9	these are the two points which we know for sure.
further study may help guide future	10	But the degree of connection and the
development of treatment modalities."	11	complex interaction between these factors is not
Did I read that correctly?	12	studied to details. Therefore, in scientific
A. That's correct.	13	literature the word "may" is used.
Q. And it says:	14	Q. What this discussion doesn't say
"These are previously	15	is that the tissue findings that you have observed
unreported findings."	16	in transvaginal mesh causes pain through the
In the first sentence of that	17	mechanisms that you've described?
paragraph, right?	18	A. Where does it say?
A. Some of the findings were	19	Q. Well, I'm saying, nowhere does
previously unreported, yes, that's correct.	20	this discussion conclude that, does it?
Q. And again, was this language "may"	21	A. It wasn't the purpose of the
used here because the statistical a	22	study. Just read the title: "Pathology of
statistically significant difference was not	23	Explanted Transvaginal Meshes."
assessed between controlled samples in the study?	24	It was a descriptive study describing
MR. ORENT: Objection.	25	the findings.
Page 163		Page 165
THE WITNESS: You have to point exact	1	Q. Okay. And, again, this article
sentence. Which, which "may"?	2	doesn't even go so far as to say that mesh could
BY MS. BYARD:	3	cause pain through the through these tissue
Q. "Polypropylene degradation may	4	response mechanisms that you've described?
play a role in the continuous	5	MR. ORENT: Objection.
inflammatory response, mesh	6	THE WITNESS: Again, this was not the
hardening and late deformations."	7	purpose of this study. Purpose of this study, if
A. Yes, so let me see. I have to	8	you read the abstract is, meshes cause
read the whole paragraph.	9	complications. This triggers excision, and they
Q. Okay.	10	have not been studied as to find reasons and
A. (Witness reviews document).	11	mechanisms of the complications.
Yeah, this is a combination. See,	12	So the purpose of this was to study and
inflammatory response, mesh hardening and late	13	see what is pathological in those specimens,
deformations.	14	abnormal. And then these abnormalities can be
This is observations which we have.	15	described and documented.
But the degree of connection between degradation	16	And then the next step would be to
and each of this is different.	17	split specimens according to specific complications
For example, if we go to continuous	18	and see statistically what each of those specific
inflammatory response, we would have to study exact	19	pathology co findings contribute, and what's the
chemicals which are produced during degradation.	20	interaction between them. So it's study details of
And how these chemicals may modify inflammatory	21	all this.
response and other thing, this is unknown.	22	BY MS. BYARD:
Therefore, it introduces a degree of uncertainty.	23	 Q. And that second step that you've
Therefore, it introduces a degree of uncertainty. Mesh hardening there will be	23 24	Q. And that second step that you've described wasn't done here?
	"We believe that these specimens contain information of the mechanisms of complications and further study may help guide future development of treatment modalities." Did I read that correctly? A. That's correct. Q. And it says: "These are previously unreported findings." In the first sentence of that paragraph, right? A. Some of the findings were previously unreported, yes, that's correct. Q. And again, was this language "may" used here because the statistical a statistically significant difference was not assessed between controlled samples in the study? MR. ORENT: Objection. Page 163 THE WITNESS: You have to point exact sentence. Which, which "may"? BY MS. BYARD: Q. "Polypropylene degradation may play a role in the continuous inflammatory response, mesh hardening and late deformations." A. Yes, so let me see. I have to read the whole paragraph. Q. Okay. A. (Witness reviews document). Yeah, this is a combination. See, inflammatory response, mesh hardening and late deformations. This is observations which we have. But the degree of connection between degradation and each of this is different. For example, if we go to continuous inflammatory response, we would have to study exact chemicals which are produced during degradation.	the last paragraph of the discussion, it says: "We believe that these specimens contain information of the mechanisms of complications and further study may help guide future development of treatment modalities." Did I read that correctly? A. That's correct. Q. And it says: "These are previously unreported findings." In the first sentence of that paragraph, right? A. Some of the findings were previously unreported, yes, that's correct. Q. And again, was this language "may" used here because the statistical a statistically significant difference was not assessed between controlled samples in the study? MR. ORENT: Objection. Page 163 THE WITNESS: You have to point exact sentence. Which, which "may"? BY MS. BYARD: Q. "Polypropylene degradation may play a role in the continuous inflammatory response, mesh hardening and late deformations." A. Yes, so let me see. I have to read the whole paragraph. Q. Okay. A. (Witness reviews document). Yeah, this is a combination. See, inflammatory response, mesh hardening and late deformations. This is observations which we have. But the degree of connection between degradation and each of this is different. For example, if we go to continuous inflammatory response, we would have to study exact chemicals which are produced during degradation.

Page 166 Page 168 1 Q. And it hasn't been done by you? 1 Q. Okay. We can do that in a second. 2 A. I'm in the process of doing, 2 Looking back here at the "Materials and 3 studying the small details of these things. 3 Methods Section," if you would, Doctor. 4 A. Yes. Because for each specific finding, 4 5 there is a degree of knowledge we have in pathology 5 Q. You write: 6 and overall in general. I mean, even for common 6 "In total, 24 specimens of 7 person, if vessel is obstructed, you know, there 7 St. Michael's Hospital patients and 8 will be no bleed going through it. It doesn't need 8 external consultation cases from 9 further studying. 9 litigation processes have been 10 10 analyzed." But how does it get obstructed? Is it 11 Did I read that correctly? 11 because there is a slowing down of the blood in A. That's correct. 12 12 there? Or because it's chemical issues affecting -a chemical product of degradation, which is 13 Q. What does, "external consultation 13 14 14 affecting blood or blood vessel, that makes it cases from litigation processes" mean? 15 15 A. Litigation cases. 16 16 Q. These lawsuits we're here to talk All these details will have to be 17 studied. I'm surprised it wasn't for 50 years, 17 about today, as well as the ones involving other 18 manufacturers? because the findings are there. 18 19 19 A. Yes. Q. Right, and that's a fair point. I 20 Q. Why is the number here 24, when 20 mean, for 50 years, pathologists have looked at polypropylene mesh, and no one has seen what you 21 we -- in your report we have 120? 21 22 A. For that specific number -- first 22 have seen and reported here, which is 23 of all, let's see if it was -- see, it was limited 23 degradation --24 to POP first. It was limited to those -- I could 24 MR. ORENT: Objection. 25 get exact information at that point, it was entered BY MS. BYARD: 25 Page 167 Page 169 1 Q. -- right? 1 in the spreadsheet. So at that point, I had A. Have they been looking at all 2 2 verified reliable data, which was on the 3 meshes? Have they been looking to answer the 3 spreadsheet for those 24 only POPs. 4 questions of complications? I mean... 4 Again, this was started much earlier 5 5 Q. My question is simpler: No one before 120. The paper became published maybe half 6 else has reported having seen what you see. 6 a year after the study was pretty much done. 7 7 MR. ORENT: Objection. That misstates O. So at the time that you submitted 8 8 this report for publication, you only had the the record. 9 THE WITNESS: That's not true. I mean, 9 completed verified data set or 24 POP specimens; is 10 there are papers which are stating some of the 10 that right? findings. 11 11 MR. ORENT: Objection. 12 THE WITNESS: With all information, I 12 Like polypropylene degradation, it was first described in the '70s. There's a degree, 13 13 would need to include it in the study, yes. It my there are different methods. Sometimes it's not be for some samples I didn't have exact information 14 14 if it was POP or sling or something else. 15 the primary purpose of the study, but in 15 16 combination, these findings were mentioned in many 16 BY MS. BYARD: 17 17 Q. If we were going to consider the 18 BY MS. BYARD: 18 120 specimens that are in your report for inclusion 19 19 in this study, how many would meet the criteria? Q. By pathologists? 20 A. Pathologists -- you mean scientist 20 And let's say for purposes of this 21 pathologists or diagnostic pathologists? 21 evaluation, that the study is not limited to POP, 22 O. Either. 22 but includes SUI product? 23 A. I don't know. We would have to 23 MR. ORENT: I just want to object to 24 look at each paper and see what's the credentials 24 your use of the term, "120 cases included in your 25 25 report." included, and what exactly is described there.

Page 170 Page 172 1 1 lightweight mesh, how many samples of each were I want to make clear, what Dr. Iakovlev 2 is talking about on page 2 of his report is his 2 included in these 24. You have examples of what 3 experience, and then he goes on to talk about his 3 area focally of the mesh was filled with loose 4 education and training. 4 connective tissue. You have statistics on the 5 His opinions are based on his 5 number of specimens that showed neural ganglia 6 experience, education and training; but are not 6 involvement. 7 based specifically on any one sample or samples. 7 I'm just trying to understand if all of And I think you're confusing him. It's not a 8 8 those same data points have been obtained and exist 9 report on 120 cases that he's offered here. 9 in the spreadsheet, or however you keep it, for the 10 MS. BYARD: Counsel, again, the 10 120 specimens that are referenced in your report? 11 speaking objections are not --11 MR. ORENT: Objection. MR. ORENT: That's not an objection. THE WITNESS: This data is obtained for 12 12 all specimens which are completed, which excision 13 That's a clarification for the record. 13 14 MS. BYARD: I'm asking him about his 14 is completed with surgical pathology report. 15 data set, which are specimens, which are what my 15 As you saw, as I mentioned, the 16 questions are directed to. 16 surgical pathology report includes all of this THE WITNESS: I can answer that 17 17 because I examine all specimens according to 18 question. 18 standardized protocol. 19 All findings described in this paper 19 So all of the findings which are 20 could be seen in those 120 or larger number of 20 described are even more since then are recorded, 21 specimen. I see them over and over again. 21 assessed, either they're there or they're not 2.2 BY MS. BYARD: 22 there. 23 Q. But you don't have -- you don't 23 How many of those have been completed, have this completed data set that you had on these 24 24 likely close to 100, but I haven't updated it 24 specimens on all 120? 25 25 recently because of an avalanche of work recently. Page 171 Page 173 1 A. We'll deal in data set. It's not 1 BY MS. BYARD: 2 a data set, it's a descriptive study which is 2 Q. Here under "Results," you mention 3 describe what findings we could find. There is no 3 that: 4 statistics in it, if you can see --4 "Available clinical records 5 I mean, there is statistics of 5 indicated mucosal exposure as a 6 frequencies in this specific 24. б reason for excision in 67 percent of 7 7 cases -- "do you see that? O. Right. 8 A. But it's not a comparison between 8 A. Yes. 9 what happens in those who experience these type of 9 O. And: 10 complication and the other one. 10 "Pain in 56 percent of cases, 11 I mean, as I said, if we take generally and both, in 33 percent of cases." 11 12 the purpose of this study, pathology of explanted 12 A. Correct. transvaginal meshes so -- and it was specifically 13 13 Q. You also say that the product --14 focused on POP devices. 14 these 24 specimens, include products from three 15 different manufacturers; do you see that? If I take all of the POP devices I 15 16 examined, there will be no -- all of these findings 16 A. Yes, I do. 17 can be seen there. And all of them can be 17 Q. Which were the three included, and if you're trying to ask me if I manufacturers? 18 18 19 selected them specifically, no. I can expect these 19 A. The earliest I received was AMS, 20 findings in any POP devices. 20 and then you, and then probably Ethicon. Q. Okay. So the study includes 21 Q. Actually, what I'm trying to 21 22 understand, Doctor, is whether the data that you 22 Boston Scientific devices? 23 had to complete this study. So, for instance, here 23 A. By the time of this study, likely. 24 you have descriptions of the fragment size. You 24 Q. Is there something you can check 25 have descriptions of the heavyweight versus 25 to confirm that for me?

	Page 174		Page 176
1	A. Yes, I should be able to do that.	1	THE WITNESS: That's correct.
2	MS. BYARD: Okay. We need to go off	2	BY MS. BYARD:
3	the record to change the tape.	3	Q. You were a paid expert for the
4	THE VIDEOGRAPHER: This marks the end	4	Plaintiffs in mesh litigation before you published
5	of media number two in the deposition of	5	this report, right?
6	Dr. Vladimir Iakovlev.	6	A. Yes.
7	We are going off the record at	7	Q. And you continue to be one today?
8	1:08 p.m.	8	A. Yes, I am.
9	OFF THE RECORD DISCUSSION	9	Q. That relationship hasn't stopped
10	THE VIDEOGRAPHER: Here begins media	10	since it began?
11	number three in the deposition of Dr. Vladimir	11	MR. ORENT: Objection.
12	Iakovlev.	12	THE WITNESS: No, but you made it sound
13	We're back on the record at 1:09 p.m.	13	as if it's my full-time job.
14	Go ahead, Counsel.	14	BY MS. BYARD:
15	MS. BYARD: Thank you.	15	Q. I didn't mean to imply that. What
16	BY MS. BYARD:	16	percentage of it is your income?
17	Q. What did you mean by excuse me	17	A. As I said, I mean, I haven't
18	if I said this actually, let me withdraw that.	18	completed billing, and I haven't last year it
19	Here, if we turn to "Disclosures", Doctor.	19	was less than 10 percent.
20	This reads:	20	Q. And this year do you have an
21	"Authors provided medical-legal	21	estimate of what percentage litigation consulting
22	consultations on the subject."	22	work for Plaintiffs will make of your overall
23	A. Yes.	23	income?
24	Q. At the time you published this	24	A. Probably more than last year,
25	article, you were working as a paid expert for	25	likely more than 10 percent. But how much more, I
23	article, you were working as a paid expert for	23	incery more than 10 percent. But now much more, 1
	Page 175		Page 177
1	Plaintiffs, right?	1	don't know. Less than 50 percent, anywhere between
2	MR. ORENT: Objection.		
	Tint. Otter i. Cojection.	2	10 to 50 percent.
3		2 3	
3 4	THE WITNESS: No, I was working as a		10 to 50 percent. Q. Here, though, in your disclosure it doesn't say which side your consulting work was
	THE WITNESS: No, I was working as a pathologist at St. Michael's Hospital. But I	3	Q. Here, though, in your disclosure
4	THE WITNESS: No, I was working as a pathologist at St. Michael's Hospital. But I provided consultations, and I was paid for time I	3 4	Q. Here, though, in your disclosure it doesn't say which side your consulting work was
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	Page 178		Page 180
1	biased in this paper, and I disclose it.	1	Q. Peers, just picking up this
2	BY MS. BYARD:	2	article, this article alone, wouldn't know that you
3	Q. It sounds like this is something	3	have testified for plaintiffs against mesh
4	you've thought about this before?	4	manufacturers in seven depositions and at two
5	A. What do you mean?	5	trials, would they?
6	Q. Did you make a conscious decision	6	MR. ORENT: Now you're misrepresenting
7	about whether or not to include that it was for one	7	the timeline and facts of this case and being
8	side versus the other that you were doing this	8	argumentative.
9	consulting work?	9	THE WITNESS: I just don't understand
10	MR. ORENT: Objection.	10	where you would see that somebody would list all
11	THE WITNESS: I always approach	11	the depositions and everything else in disclosure.
12	everything trying to be as neutral as possible, and	12	Disclosure, as I said, if it's funded,
13	give neutral information. I mean, it's always in	13	usually the funding agencies provide it.
14	my head.	14	If there are other conflicts of
15	BY MS. BYARD:	15	interest, they just provide it through best sort of
16	Q. So did you have a discussion with	16	neutral, or shortest way, or depending on the
17	Dr. Carey and Dr. Steege about whether you should	17	paper.
18	put which side your consulting work was on?	18	This paper wasn't funded by anyone. I
19	A. No, I don't remember if we	19	received the specimens from different sources, and
20	discussed the specifics. I mean, usually, it's	20	we analyzed it, and there was no additional work to
21	disclosed conflict of interest, and people describe	21	what usually pathology laboratory does.
22	them as the way they think is most appropriate.	22	BY MS. BYARD:
23	Sometimes journal has specific requirements, how	23	Q. So the words "for plaintiffs" does
24	you describe it.	24	not appear in this disclosure, right?
25	Q. So, for instance, if a study a	25	MR. ORENT: Objection.
			Page 181
1 2	Page 179 clinical study, let's say, was funded by Boston Scientific, it would indicate that it was funded by	1 2	Page 181 THE WITNESS: No. And, essentially, it was part of the purpose not to bias it in this way.
	clinical study, let's say, was funded by Boston		THE WITNESS: No. And, essentially, it
2	clinical study, let's say, was funded by Boston Scientific, it would indicate that it was funded by	2	THE WITNESS: No. And, essentially, it was part of the purpose not to bias it in this way.
2	clinical study, let's say, was funded by Boston Scientific, it would indicate that it was funded by Boston Scientific, if the author was following,	2 3	THE WITNESS: No. And, essentially, it was part of the purpose not to bias it in this way. As I said, there might be multiple
2 3 4	clinical study, let's say, was funded by Boston Scientific, it would indicate that it was funded by Boston Scientific, if the author was following, what you've described as the best practices, right?	2 3 4	THE WITNESS: No. And, essentially, it was part of the purpose not to bias it in this way. As I said, there might be multiple biases. Plaintiff, not plaintiff, the manufacturer
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2 3 4 5 6	clinical study, let's say, was funded by Boston Scientific, it would indicate that it was funded by Boston Scientific, if the author was following, what you've described as the best practices, right? MR. ORENT: Objection. THE WITNESS: If a study is funded by a	2 3 4 5 6	THE WITNESS: No. And, essentially, it was part of the purpose not to bias it in this way. As I said, there might be multiple biases. Plaintiff, not plaintiff, the manufacturer can be presenting different type of biases. Plaintiffs have claims that it caused
2 3 4 5 6 7	clinical study, let's say, was funded by Boston Scientific, it would indicate that it was funded by Boston Scientific, if the author was following, what you've described as the best practices, right? MR. ORENT: Objection. THE WITNESS: If a study is funded by a specific agency, there might be a specific	2 3 4 5 6 7	THE WITNESS: No. And, essentially, it was part of the purpose not to bias it in this way. As I said, there might be multiple biases. Plaintiff, not plaintiff, the manufacturer can be presenting different type of biases. Plaintiffs have claims that it caused damage. But at the same time, there might be
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	Page 182		Page 184
1	researcher or couldn't.	1	THE WITNESS: Have you ever seen
2	So this is how it is done. It is	2	BY MS. BYARD:
3	disclosed to the most neutral way, and then it's up	3	Q. Does the word appear there,
4	to readers to see if the paper, paper itself,	4	Doctor?
5	contains any information that it could have been	5	A. No, it's not
6	biased.	6	MR. ORENT: Counsel, you're not
7	BY MS. BYARD:	7	entitled to badger the witness. He's answered your
8	Q. And part of how you evaluate that	8	question four times. You're trying to clearly get
9	is by knowing who funded the study?	9	your bullet point, you can read the article just as
10	MR. ORENT: Objection.	10	well as any of us.
11	THE WITNESS: No, no. Not exactly.	11	The Rules of Civil Procedure do not
12	BY MS. BYARD:	12	permit badgering of the witness, so move on.
13	Q. Part of the way that you do that	13	MS. BYARD: It's my deposition and I'm
14	is knowing who prior consulting work was for?	14	entitled to get answers to my questions.
15	MR. ORENT: Objection.	15	BY MS. BYARD:
16	THE WITNESS: I would say not who	16	Q. My question is simply this, Doctor:
17	funded the study, but if the funding agency could	17	Under the disclosure, in your study
18	have an effect or control on the researchers,	18	with Dr. Carey and Dr. Steege, it says, "authors
19	that's the most important question.	19	provided medical-legal consultations on this
20	I mean, most of the clinical studies or	20	subject." It does not say "for plaintiffs," does
21	other are funded, because it's such an expensive	21	it?
22	but then it's up to readers to see if funding	22	A. No, it does not
23	agency could control, could have an effect. It may	23	MR. ORENT: Objection.
24	be not direct.	24	THE WITNESS: state. I could have
25	I mean, like you focusing on	25	been providing for both Plaintiffs and
23	i inean, fixe you locusing on	23	been providing for both Filaments and
		1	
	Page 183		Page 185
1	Page 183 manufacturers. But there are some non-for-profit	1	Page 185 manufacturers.
1 2		1 2	
	manufacturers. But there are some non-for-profit		manufacturers.
2	manufacturers. But there are some non-for-profit organizations which are funding with grants and	2	manufacturers. BY MS. BYARD:
2 3	manufacturers. But there are some non-for-profit organizations which are funding with grants and everything else, and there is a competition to get	2 3	manufacturers. BY MS. BYARD: Q. As a reader, I would have no way
2 3 4	manufacturers. But there are some non-for-profit organizations which are funding with grants and everything else, and there is a competition to get these grants and so forth. So you might be biased	2 3 4	manufacturers. BY MS. BYARD: Q. As a reader, I would have no way of knowing which side your testimony had been paid
2 3 4 5	manufacturers. But there are some non-for-profit organizations which are funding with grants and everything else, and there is a competition to get these grants and so forth. So you might be biased to produce better results in order to renew a grant	2 3 4 5	manufacturers. BY MS. BYARD: Q. As a reader, I would have no way of knowing which side your testimony had been paid for by reading your article?
2 3 4 5 6	manufacturers. But there are some non-for-profit organizations which are funding with grants and everything else, and there is a competition to get these grants and so forth. So you might be biased to produce better results in order to renew a grant and so forth.	2 3 4 5 6	manufacturers. BY MS. BYARD: Q. As a reader, I would have no way of knowing which side your testimony had been paid for by reading your article? MR. ORENT: Objection.
2 3 4 5 6 7	manufacturers. But there are some non-for-profit organizations which are funding with grants and everything else, and there is a competition to get these grants and so forth. So you might be biased to produce better results in order to renew a grant and so forth. So this is a different bias. It might	2 3 4 5 6 7	manufacturers. BY MS. BYARD: Q. As a reader, I would have no way of knowing which side your testimony had been paid for by reading your article? MR. ORENT: Objection. THE WITNESS: You shouldn't have to
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	manufacturers. But there are some non-for-profit organizations which are funding with grants and everything else, and there is a competition to get these grants and so forth. So you might be biased to produce better results in order to renew a grant and so forth. So this is a different bias. It might be even stronger than just financial bias. It's the same financial bias, because you are acquiring grants from there. Again, it's up to the readers to decide if that specific funding agency could have an effect. Medical-legal consultation means that somebody provided opinion and was paid. So this can create a bias, and it's up to readers, again, go and see if there is any indication that there was a bias. And I provided bias that, that possibility. BY MS. BYARD: Q. Let's see what we can agree on, because you've said a lot on this. All I want to know is whether the word	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	manufacturers. BY MS. BYARD: Q. As a reader, I would have no way of knowing which side your testimony had been paid for by reading your article? MR. ORENT: Objection. THE WITNESS: You shouldn't have to know. You should be able to go through the paper and try to find clues if there was a bias. Because that's the whole point of critical appraisal in the literature. If somebody tells you from the beginning, that this study is biased because it was paid and so forth, would you read this article? BY MS. BYARD: Q. Is that part of the reason why you didn't disclose which side you were on? A. No, I'm just saying that I never seen a single paper where the disclosure was formulated the way you're trying to introduce. I have never seen when it states that somebody was consulted on side of plaintiff. Maybe
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	manufacturers. But there are some non-for-profit organizations which are funding with grants and everything else, and there is a competition to get these grants and so forth. So you might be biased to produce better results in order to renew a grant and so forth. So this is a different bias. It might be even stronger than just financial bias. It's the same financial bias, because you are acquiring grants from there. Again, it's up to the readers to decide if that specific funding agency could have an effect. Medical-legal consultation means that somebody provided opinion and was paid. So this can create a bias, and it's up to readers, again, go and see if there is any indication that there was a bias. And I provided bias that, that possibility. BY MS. BYARD: Q. Let's see what we can agree on, because you've said a lot on this. All I want to know is whether the word "for plaintiffs" appears in this sentence?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	manufacturers. BY MS. BYARD: Q. As a reader, I would have no way of knowing which side your testimony had been paid for by reading your article? MR. ORENT: Objection. THE WITNESS: You shouldn't have to know. You should be able to go through the paper and try to find clues if there was a bias. Because that's the whole point of critical appraisal in the literature. If somebody tells you from the beginning, that this study is biased because it was paid and so forth, would you read this article? BY MS. BYARD: Q. Is that part of the reason why you didn't disclose which side you were on? A. No, I'm just saying that I never seen a single paper where the disclosure was formulated the way you're trying to introduce. I have never seen when it states that somebody was consulted on side of plaintiff. Maybe they exist, but I've never seen it.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	manufacturers. But there are some non-for-profit organizations which are funding with grants and everything else, and there is a competition to get these grants and so forth. So you might be biased to produce better results in order to renew a grant and so forth. So this is a different bias. It might be even stronger than just financial bias. It's the same financial bias, because you are acquiring grants from there. Again, it's up to the readers to decide if that specific funding agency could have an effect. Medical-legal consultation means that somebody provided opinion and was paid. So this can create a bias, and it's up to readers, again, go and see if there is any indication that there was a bias. And I provided bias that, that possibility. BY MS. BYARD: Q. Let's see what we can agree on, because you've said a lot on this. All I want to know is whether the word	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	manufacturers. BY MS. BYARD: Q. As a reader, I would have no way of knowing which side your testimony had been paid for by reading your article? MR. ORENT: Objection. THE WITNESS: You shouldn't have to know. You should be able to go through the paper and try to find clues if there was a bias. Because that's the whole point of critical appraisal in the literature. If somebody tells you from the beginning, that this study is biased because it was paid and so forth, would you read this article? BY MS. BYARD: Q. Is that part of the reason why you didn't disclose which side you were on? A. No, I'm just saying that I never seen a single paper where the disclosure was formulated the way you're trying to introduce. I have never seen when it states that somebody was consulted on side of plaintiff. Maybe

	Page 186		Page 188
1	such and such company"?	1	here.
2	MR. ORENT: Objection.	2	A. Coauthors. Yes, you read it
3	THE WITNESS: Usually it's financial	3	correct.
4	disclosure. "This funding was sponsored or funded	4	Q. Here there is a discussion of,
5	in part by this manufacturer" or something like	5	again, looking at specimens. This time of
6	this.	6	transvaginal slings; do you see that?
7	I don't remember specifically wording	7	A. Yes, this was limited to slings.
8	like you've just said. Usually they describe	8	Q. How many specimens were included
9	funding agency or manufacturer in terms of funding	9	in this write-up? I thought I saw 63 in Table 1.
10	source.	10	A. Yes. So a total number was 63,
11	EXHIBIT NO. 1199: Abstract entitled,	11	18 were retropubic and 45 were transobturator.
12	"Pathological Findings of Transvaginal	12	Q. Here, for the 63 studies, you used
13	Polypropylene Slings Explanted for Late	13	scar tissue from non-mesh excisions as a reference
14	Complications: Mesh is Not Inert," by	14	control?
15	Dr. V. Iakovlev, Dr. G. Mekel and Dr.	15	A. Just general understanding, how it
16	J. Blaivas	16	looks and what are the pathological findings, yes.
17	BY MS. BYARD:	17	Q. There wasn't any sort of objective
18	Q. I'm handing you Exhibit 1199.	18	measuring of the number of nerves, or the number of
19	And this is another publication of	19	blood vessels like we saw in your hernia mesh study
20	yours from this year, right, Doctor?	20	with Dr. Bendavid, right?
21	A. That's correct.	21	A. No. In this case, scar tissue was
22	Q. And this is an article that you	22	used more for a reference for inflammation, for
23	published with doctor I'm sorry an abstract	23	foreign body reaction and other mesh-related
24	that you published with Dr. Mekel and Dr. Blaivas,	24	changes.
25	right?	25	Q. I wanted to understand the
25	right:	25	Q. I wanted to understand the
	Page 187		Page 189
	<u> </u>		rage 10)
1	A. That's correct.	1	sentence two, three lines in, under "Interpretation
1 2		1 2	
	A. That's correct.	l .	sentence two, three lines in, under "Interpretation
2	A. That's correct.Q. And Dr. Blaivas is a paid	2	sentence two, three lines in, under "Interpretation of Results" where you write:
2	A. That's correct. Q. And Dr. Blaivas is a paid Plaintiffs' expert, too, right?	2 3	sentence two, three lines in, under "Interpretation of Results" where you write: "In contrast, mature scar
2 3 4	A. That's correct.Q. And Dr. Blaivas is a paidPlaintiffs' expert, too, right?A. I know that he gave his opinion to	2 3 4	sentence two, three lines in, under "Interpretation of Results" where you write: "In contrast, mature scar tissue after non-mesh surgeries does
2 3 4 5	A. That's correct. Q. And Dr. Blaivas is a paid Plaintiffs' expert, too, right? A. I know that he gave his opinion to some cases.	2 3 4 5	sentence two, three lines in, under "Interpretation of Results" where you write: "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation."
2 3 4 5 6	A. That's correct. Q. And Dr. Blaivas is a paid Plaintiffs' expert, too, right? A. I know that he gave his opinion to some cases. Q. For the Plaintiffs, correct?	2 3 4 5 6	sentence two, three lines in, under "Interpretation of Results" where you write: "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that?
2 3 4 5 6 7	A. That's correct. Q. And Dr. Blaivas is a paid Plaintiffs' expert, too, right? A. I know that he gave his opinion to some cases. Q. For the Plaintiffs, correct? A. I don't know if only for the	2 3 4 5 6 7	sentence two, three lines in, under "Interpretation of Results" where you write: "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you
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2 3 4 5 6 7 8 9	A. That's correct. Q. And Dr. Blaivas is a paid Plaintiffs' expert, too, right? A. I know that he gave his opinion to some cases. Q. For the Plaintiffs, correct? A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of	2 3 4 5 6 7 8	sentence two, three lines in, under "Interpretation of Results" where you write: "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in.
2 3 4 5 6 7 8 9	A. That's correct. Q. And Dr. Blaivas is a paid Plaintiffs' expert, too, right? A. I know that he gave his opinion to some cases. Q. For the Plaintiffs, correct? A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of this.	2 3 4 5 6 7 8 9	sentence two, three lines in, under "Interpretation of Results" where you write: "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in. MR. ORENT: Paragraph 2.
2 3 4 5 6 7 8 9 10	A. That's correct. Q. And Dr. Blaivas is a paid Plaintiffs' expert, too, right? A. I know that he gave his opinion to some cases. Q. For the Plaintiffs, correct? A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of this. Q. So of the cases that you're aware	2 3 4 5 6 7 8 9 10	sentence two, three lines in, under "Interpretation of Results" where you write: "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in. MR. ORENT: Paragraph 2. THE WITNESS: "In contrast, mature scar
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2 3 4 5 6 7 8 9 10 11 12	A. That's correct. Q. And Dr. Blaivas is a paid Plaintiffs' expert, too, right? A. I know that he gave his opinion to some cases. Q. For the Plaintiffs, correct? A. I don't know if only for the Plaintiffs. For those I know for Plaintiffs, it could have been giving opinion for manufacturers of this. Q. So of the cases that you're aware of, he testified for the Plaintiffs? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13	sentence two, three lines in, under "Interpretation of Results" where you write: "In contrast, mature scar tissue after non-mesh surgeries does not show inflammation." Do you see that? A. So can you point where you Q. Sure. Underneath "Interpretation of Results," the third sentence in. MR. ORENT: Paragraph 2. THE WITNESS: "In contrast, mature scar after non-mesh surgeries does not show inflammation." Yes, that's correct.
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Page 190 Page 192 There are multiple differences between 1 Q. And we don't really need to go 1 2 into all that, because I do understand that from 2 a scar without mesh and a scar with mesh. 3 your deposition before. I appreciate that, thank 3 BY MS. BYARD: 4 you, Doctor. 4 Q. In this discussion where you say, 5 5 "scar tissue from non-mesh excisions were used as What I'm trying to understand is when 6 in time you will stop seeing inflammation in the 6 reference controls," are you referring to the scar 7 development of scar tissue? 7 tissue that you used from the abdominal wall in the 8 A. Sometime after few weeks of 8 Dr. Bendavid study, or were you specifically 9 healing. 9 referencing scar tissue from vaginal mesh 10 10 excisions? Q. How long will it take for nerves 11 A. In this case, specifically for 11 to begin to ingrow in scar tissue? 12 vaginal mesh. I mean, they were not grouped 12 A. Also happens within first few together, but either with the specimens, sometimes 13 13 weeks of healing. 14 I received just scar tissue without mesh outside. 14 Q. First few weeks -- are we talking 15 one to four weeks, or are we talking one to 15 Sometimes it's just a scar excision and surgeon six weeks? What's the window that's accepted? 16 identifies it as a scar excision. Or sometimes we 16 17 A. It's very variable. It depends on receive it in the course of some surgeries in 17 18 St. Michael's Hospital, so I visually know what it 18 individuals, conditions, repetitive injury. And 19 19 all this process are continuing from about day looks like. 20 Q. And then you go on to write that: 20 three to anywhere six, eight weeks, maybe longer. "Surprisingly, easily visible 21 21 If there is continuous injury, it may repeat itself in the microscope, it has been 22 22 during years. 23 overlooked for 50 years." 23 Q. So if a patient, for instance, And there you're describing what you've 24 24 complained of immediate postoperative pain, would coined as a term, "degradation bark"; right? 25 25 it be fair to say that nerve ingrowth in mesh Page 191 Page 193 1 structures could not be the source of that pain, 1 A. Yes, that's correct. The 2 2 because nerves could not yet appear growing within degradation layer was not described as it appears 3 the mesh structure? 3 in the light microscope. 4 A. Yes, that's correct. 4 Q. And that's what I was getting at 5 5 Q. Okay. And here you talk about earlier. On the one hand you told me degradation 6 potential sources of pain, you write: 6 of polypropylene has been described since the 7 7 "Within these mini compartments, 1970s. And then here, in this abstract that you 8 8 the innervated tissue is exposed to publish with Dr. Blaivas, you say it's been 9 9 potential sources of pain such as overlooked for 50 years? I was trying to reconcile 10 compression, stretching, 10 inflammation, ischemia, etcetera." 11 11 A. Well, it's clear. This states 12 12 A. That's correct. about microscopic appearance and the cross-sections 13 Q. But you would agree these 13 in a light microscope, and I'm talking about detection of degradation by other means, either 14 potential sources of pain are also present in scar 14 15 scanning electron microscopy or mechanical testing. 15 tissue where there is compression, stretching of 16 the scar tissue, inflammation in the scar tissue, 16 So this is specifically for microscopic appearance 17 ischemia, etcetera, wouldn't you? 17 and light microscope. 18 18 Q. So if you were going to complete A. No. 19 19 the following sentence: "I was the first MR. ORENT: Objection. 20 THE WITNESS: No, I wouldn't agree. 20 pathologist to observe..." what? 21 There is no inflammation, there is no edema, scar 21 MR. ORENT: Objection to form. 22 tissue doesn't show conditional edema. Scar is 22 THE WITNESS: I don't know if I was 23 pliable, it can change over time. So if there is 23 first one. 24 shrinking, it will slowly change because it's 24 BY MS. BYARD: 25 25 native tissue. Q. You were the first one to report

	Page 194		Page 196
1	findings on degradation of degradation bark	1	BY MS. BYARD:
2	under polarized light in microscopic observation?	2	Q. So you could design an experiment
3	MR. ORENT: Objection.	3	where you looked at incidences of exposure, and
4	THE WITNESS: I'm the first one who is	4	whether or not there was curling, and also a
5	describing light microscopy features of	5	control sample where there's curling but not
6	polypropylene degradation. So that would be a full	6	exposure, right?
7	definition. To my knowledge, I am the first one.	7	A. I can tell you for sure, if I see
8	BY MS. BYARD:	8	the edge rotated towards, the mesh was curled
9	Q. To your knowledge, nobody else has	9	100 percent.
10	done it besides you up until this point?	10	Some cases I see curling completely
11	A. Nobody published.	11	outside of the exposure if there's no exposure
12	Q. You continue:	12	surgically described. So, based on these two
13	"From mesh exposure an	13	observations, I can state if curling occurs close
14	important finding was that sling	14	to the surface, the edge is prone to be exposed.
15	edges rotated or curled towards the	15	Q. You can't say that exposures occur
16	surface at the exposure sites."	16	at a statistically significant rate with curled
17	Tell me what you meant by that.	17	mesh edges?
18	THE WITNESS: Sometimes when a reason	18	A. But
19	for excision is mesh exposure, the mesh, if you can	19	Q. Over non-curled mesh edges?
20	see the mesh is rotated if this is the mucosal	20	A. What do you compare it with? You
21	surface, I can see it's rotated. I can see the	21	have to clinical experiment would be, curled
22	curl. If it is a big enough piece and well	22	meshes are placed right under the mucosa, and then
23	oriented then I can see it.	23	the rate of exposure is measured. Can you do that?
24	BY MS. BYARD:	24	You can't.
25	Q. Based on your observations to	25	Every time I see it's curled at the
	Daga 10E		Daga 107
	Page 195		Page 197
1	date, are you able to say whether the exposure of	1	mucosa, it's exposed; 100 percent, as I said. If
2	date, are you able to say whether the exposure of the mesh causes the curling or whether the curling	2	mucosa, it's exposed; 100 percent, as I said. If it's not at the mucosa, it cannot be exposed
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	Page 198		Page 200
1	degradation products."	1	consulting in Exhibit 1199, right?
2	Did I read that correctly?	2	A. Well, this is
3	A. That is correct.	3	MR. ORENT: Objection.
4	Q. And here again, what this	4	THE WITNESS: clearly disclosed.
5	conclusion reinforces, is that there's a need for a	5	BY MS. BYARD:
6	further study to understand the details of the	6	Q. Where?
7	mechanisms of actions of the relationships between	7	A. "Some external consultations sent
8	degradation and inflammation, as well as mesh	8	for litigation purposes" see, again, this was a
9	hardening, and whether any chemical degradation	9	very structured way of submitting abstract. I
10	products are produced or what they are, right?	10	didn't have much flexibility to put in. I had a
11	MR. ORENT: Objection.	11	drop-down menu for funding only.
12	THE WITNESS: That's correct. Because	12	See if it's see, funding, subject,
13	what we know? We know that some patients present	13	ethics committee and everything else, I could enter
14	with complaints six or eight years after the	14	only specific amount of information in the
15	insertion.	15	drop-down menu. So I tried my best to disclose as
16	So the only thing which changes over	16	much as I can.
17	time is the degree of degradation. So degradation	17	Q. So your testimony is that for
18	layer or bark is getting thicker, so it's inflamed	18	1198 and 1199, there was a free text field you
19	and so forth.	19	could type in?
20	So from what we know now, the only late	20	MR. ORENT: Objection.
21	factor which happens around the mesh or to the mesh	21	THE WITNESS: To a certain degree I
22	is degradation. So those changes which occur later	22	don't remember exactly now but I mean it was
23	on, will have more larger component of	23	which one?
24	degradation within the mechanisms of this.	24	BY MS. BYARD:
25	But how exactly it occurs, then again,	25	Q. The one we looked at before where
	But now exactly it occurs, then again,		Q. The one we looked at before where
	Page 199		Page 201
1	Page 199 it needs to be studied. Or, if I observe a bark or	1	Page 201 you published with Dr. Carey?
1 2		1 2	
	it needs to be studied. Or, if I observe a bark or		you published with Dr. Carey?
2	it needs to be studied. Or, if I observe a bark or degradation layer, I can see the cracks in it. I know that they're internal forces which shrink it. But how much of that, how all these forces work, I	2	you published with Dr. Carey? A. This one was free text, just submitted paper. It was just, um, paragraph disclosures, this one was more restricted.
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2 3 4 5	it needs to be studied. Or, if I observe a bark or degradation layer, I can see the cracks in it. I know that they're internal forces which shrink it. But how much of that, how all these forces work, I mean, it all needs to be studied.	2 3 4 5	you published with Dr. Carey? A. This one was free text, just submitted paper. It was just, um, paragraph disclosures, this one was more restricted. Q. And so but you typed in the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	it needs to be studied. Or, if I observe a bark or degradation layer, I can see the cracks in it. I know that they're internal forces which shrink it. But how much of that, how all these forces work, I mean, it all needs to be studied. BY MS. BYARD: Q. You also write here one sentence before this: "The compartmentalizing nature of the meshes and nerve ingrowth might create a background for the pain mechanisms." Do you see that? It's just one sentence before the one we just read. A. Can you point on your copy? Q. Yes, here. A. Yes, that's correct. Q. Again, you've used this word "may"? A. Again, because all these Q. That's my only question. That's	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	you published with Dr. Carey? A. This one was free text, just submitted paper. It was just, um, paragraph disclosures, this one was more restricted. Q. And so but you typed in the words, "Some specimens were received as external consultations sent for litigation purposes." A. That's correct. Yes, I did it. Q. And again, the word "for Plaintiffs" does not appear here, does it? A. No. But, as I said, we discussed it before. MS. BYARD: We need to take a break now for everyone. THE WITNESS: So it's 20 to 2:00. Do we take a break and then come back? I can still go on for another hour or so. MS. BYARD: Do you mind if we discuss this off the record? MR. ORENT: Yes, sure. THE VIDEOGRAPHER: Going off the record
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	it needs to be studied. Or, if I observe a bark or degradation layer, I can see the cracks in it. I know that they're internal forces which shrink it. But how much of that, how all these forces work, I mean, it all needs to be studied. BY MS. BYARD: Q. You also write here one sentence before this: "The compartmentalizing nature of the meshes and nerve ingrowth might create a background for the pain mechanisms." Do you see that? It's just one sentence before the one we just read. A. Can you point on your copy? Q. Yes, here. A. Yes, that's correct. Q. Again, you've used this word "may"? A. Again, because all these Q. That's my only question. That's the word that you've used, right? A. Well, it's written.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	you published with Dr. Carey? A. This one was free text, just submitted paper. It was just, um, paragraph disclosures, this one was more restricted. Q. And so but you typed in the words, "Some specimens were received as external consultations sent for litigation purposes." A. That's correct. Yes, I did it. Q. And again, the word "for Plaintiffs" does not appear here, does it? A. No. But, as I said, we discussed it before. MS. BYARD: We need to take a break now for everyone. THE WITNESS: So it's 20 to 2:00. Do we take a break and then come back? I can still go on for another hour or so. MS. BYARD: Do you mind if we discuss this off the record? MR. ORENT: Yes, sure. THE VIDEOGRAPHER: Going off the record
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-	Page 202		Page 204
1	record at 2:16 p.m.	1	My question for you is whether this 130
2	BY MS. BYARD:	2	meshes includes Gore-Tex and combined designs in
3	Q. Doctor, I'm handing you	3	addition to polypropylene mesh?
4	Exhibit 1200. I'll ask if you recognize that?	4	A. No. This would just be POP and
5	A. Yes, I do.	5	knitted polypropylene meshes.
6	Q. This was an abstract that you	6	Q. And then you describe here some
7	published this year with the let me start over.	7	findings that we've already discussed in
8	This was an abstract that was published this year?	8	relationship to your other article with Dr. Carey,
9	A. Yes, that's correct.	9	correct?
10	Q. The title is, "Explanted Surgical	10	A. That's correct.
11	Meshes: What Pathologists and Industry Failed to	11	Q. Are there any findings reported
12	Do for Over 50 Years"; is that right?	12	here that are different, or in addition to the
13	A. For 50 years.	13	findings reported in the full length article that
14	Q. Thank you. Under "Objective" you	14	you authored with Dr. Carey and Dr. Steege?
15	write, three sentences in:	15	A. Um, this was a smaller abstract
16	"Estimated millions of devices	16	which, as you can see, combine transvaginal meshes,
17	have been excised over the years,	17	slings and POP devices and hernia meshes. So this
18	however, the study material remain	18	is more of a descriptive study of all meshes,
19	largely ignored and the mechanisms	19	irrespective of their anatomical location. Where
20	of complications are still poorly	20	other papers were concentrated on specific type of
21	understood".	21	transvaginal locations, whether slings or POP devices.
22	A. That's correct.	22	Q. And so it wouldn't be true to say
23	Q. Under "method" you write:	23	that the 120 specimens that you described in your
24	"130 meshes excised from	24	litigation report are all included in this
25	different anatomical sites were	25	abstract, correct?
			,
	Page 203		Page 205
1	studied in search of features	1	A. You see the abstract was written
2	explaining the complications."	2	earlier, a few months earlier so
3	Did I read that correctly?	3	0 77 1 100
	THE WITNESS TO 4		Q. The reason why we get to 130
4	THE WITNESS: That's correct.	4	Q. The reason why we get to 130 specimens is because you've included other types of
4 5	BY MS. BYARD:		
		4	specimens is because you've included other types of
5	BY MS. BYARD:	4 5	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh,
5 6	BY MS. BYARD: Q. Did these 130 mesh specimens	4 5 6	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right?
5 6 7	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh?	4 5 6 7	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was
5 6 7 8	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes.	4 5 6 7 8	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my
5 6 7 8 9	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other	4 5 6 7 8 9	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool.
5 6 7 8 9	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh?	4 5 6 7 8 9	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these
5 6 7 8 9 10 11	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of	4 5 6 7 8 9 10	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh?
5 6 7 8 9 10 11	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or	4 5 6 7 8 9 10 11 12	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had
5 6 7 8 9 10 11 12 13	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight,	4 5 6 7 8 9 10 11 12	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was
5 6 7 8 9 10 11 12 13	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or	4 5 6 7 8 9 10 11 12 13	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this
5 6 7 8 9 10 11 12 13 14	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the	4 5 6 7 8 9 10 11 12 13 14	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this Q. Okay.
5 6 7 8 9 10 11 12 13 14 15	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication.	4 5 6 7 8 9 10 11 12 13 14 15	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this Q. Okay. A roughly. So I think I had 97
5 6 7 8 9 10 11 12 13 14 15 16 17	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed	4 5 6 7 8 9 10 11 12 13 14 15 16	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this Q. Okay. A roughly. So I think I had 97 transvaginal meshes. If it was a different number,
5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal	4 5 6 7 8 9 10 11 12 13 14 15 16 17	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this Q. Okay. A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But
5 6 7 8 9 10 11 12 13 14 15 16 17 18	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations.	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this Q. Okay. A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes.
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations. Q. And your report in the litigation	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this Q. Okay. A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes. Q. Okay. So including sources of
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations. Q. And your report in the litigation which has been marked as Exhibit 1196, you wrote	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this Q. Okay. A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes. Q. Okay. So including sources of specimens from provided to you from Plaintiffs'
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations. Q. And your report in the litigation which has been marked as Exhibit 1196, you wrote that the explanted transvaginal mesh specimens that	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this Q. Okay. A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes. Q. Okay. So including sources of specimens from provided to you from Plaintiffs' counsel in the mesh litigation?
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MS. BYARD: Q. Did these 130 mesh specimens include both hernia mesh and transvaginal mesh? A. Yes. At that time, yes. Q. Did they include any other anatomical sites or types of polypropylene mesh? A. What do you mean "types of polypropylene?" Polypropylene mesh is polypropylene mesh. Do you mean lightweight, heavyweight or Q. I was just thinking of the indication. A. At that time, all 130 were needed polypropylene meshes from hernia or a transvaginal locations. Q. And your report in the litigation which has been marked as Exhibit 1196, you wrote that the explanted transvaginal mesh specimens that you've examined include slings and POP devices,	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	specimens is because you've included other types of polypropylene mesh besides transvaginal mesh, right? A. At that point, yes. This was total amount of polypropylene meshes I had in my specimen pool. Q. Can you tell me how many of these 130 specimens were transvaginal mesh? A. Just below 100. I think you had the table which I supplied in July that was representing approximately the time of this Q. Okay. A roughly. So I think I had 97 transvaginal meshes. If it was a different number, then probably it was different at that point. But what I recall was 97 transvaginal meshes. Q. Okay. So including sources of specimens from provided to you from Plaintiffs' counsel in the mesh litigation? MR. ORENT: Objection.

	Page 206		Page 208
1	A. There was 97, yes.	1	Polypropylene Meshes: A Finding
2	Q. You conclude that:	2	Overlooked for Decades," by Dr. V. Iakovlev,
3	"General lack of interest	3	Dr. S. Guelcher, Dr. R. Bendavid.
4	created a paradoxical gap of	4	BY MS. BYARD:
5	knowledge in the presence of	5	Q. Exhibit 1201 will be passed to you
6	abundant study material and readily	6	here momentarily.
7	available tools."	7	MR. ORENT: This is 1201 you said?
8	Right.	8	MS. BYARD: Correct.
9	A. That's correct.	9	BY MS. BYARD:
10	Q. You continue:	10	Q. The title of 1201 well, first I
11	"The newly described findings	11	should ask, this is familiar to you, right?
12	need to be studied in correlation	12	A. Yes. That's the same conference,
13	with clinical symptoms to guide	13	the same submission process. The same journal, the
14	future developments."	14	same issue.
15	Correct?	15	Q. The title of this abstract is:
16	THE WITNESS: That's correct.	16	"In vivo Degradation of Surgical Polypropylene
17	BY MS. BYARD:	17	Meshes: A Finding Overlooked for Decades."
18	Q. This study doesn't describe any	18	A. That's correct.
19	correlation of your histological findings with	19	Q. And this is published with
20	clinical symptoms, does it?	20	Dr. Scott Guelcher and Dr. Bendavid, right?
21	A. No, not directly.	21	MR. ORENT: Guelcher.
22	Q. There is no conflict of interest	22	THE WITNESS: Guelcher.
23	disclosure in Exhibit 1200, right?	23	BY MS. BYARD:
24	A. It was provided later in the	24	Q. Thank you. And Dr. Guelcher is a
25	presentation, I believe. It's just the way it was	25	paid Plaintiffs' expert like you, correct?
1	published.	1	MR. ORENT: Objection.
2	I think I gave disclosures during	2	THE WITNESS: Yes. He served as expert
3	submission. But the way they publish it, there's	3	witness.
4	no disclosure. I can see there's no other	4	BY MS. BYARD:
5	disclosures for any other abstracts.	5	Q. On the Plaintiffs' side, as far as
6	Q. There's not a disclosure that	6	you know, right?
7	appears here in Exhibit 1200, is there?	7	A. From those cases we've been
8	A. On the paper, no.	8	involved together, yes, he was on Plaintiffs' side.
9	MR. ORENT: Objection.	9	Could have been on manufacturer side for something
10	THE WITNESS: But it doesn't mean that	10	else.
11	it was not provided, or was not disclosed elsewhere	11	Q. But as far as you know, it's been
12	assuming for presentation.	12	on the Plaintiffs' side, right?
13	If it's a presentation, I give slide	13	MR. ORENT: Objection.
14	with some disclosure, which is usually first slide	14	THE WITNESS: I don't make the
15	before the presentation.	15	distinction. Because as I said, I mean, this is up
16	BY MS. BYARD:	16	to me to decide, or any other reader if there is a
17	Q. Okay. If you're able to find the	17	bias on which side and how it is presented.
18	disclosure form that you think you might have	18	BY MS. BYARD:
19	completed for this, would you provide it to counsel	19	Q. My only question is, as far as you
20	for me?	20	know, he served as a testifying expert for
21	A. I could not have it, because it	21	Plaintiffs against mesh manufacturers, correct?
22	was electronic submission.	22	A. That's correct.
23	Q. Okay.	23	Q. Under "Objectives", you write:
24	EXHIBIT NO. 1201: Abstract entitled,	24	"Surgical polypropylene meshes
	"In-vivo Degradation of Surgical	25	introduced over 50 years ago are
25	iii-vivo Degradation of Surgical		

53 (Pages 206 to 209)

	Page 210		Page 212
1	excised in up to 10 percent for	1	A. Yes.
2	complications."	2	Q. That study has not yet been
3	Did I read that correctly?	3	completed, true?
4	A. Yes.	4	A. What exactly? Which study?
5	Q. Is this a statistic for hernia	5	Q. The study of the role of
6	mesh or for transvaginal mesh?	6	degradation in the development of complications?
7	A. This is difficult now to remember.	7	A. It doesn't state it there as a
8	Because it was based on all of those. So "up to"	8	study.
9	means the highest number I could see in	9	Q. You write:
10	sufficiently reliable source.	10	"The discovery opens the door
11	Q. Sometimes the rate is lower than	11	to study the role of degradation in
12	that in the reported literature, true?	12	the development of complications".
13	A. It's a range. I mean, if you take	13	A. Yes. But it doesn't state that we
14	small sample size, one single mesh which has not	14	have a study ongoing to do that. "Study" is used
15	been excised, you don't have any rate. If a sample	15	as a verb here not as a noun.
16	size goes larger, then you get more or less	16	Q. You haven't yet published anything
17	representative sample of the whole population.	17	on the role of degradation and the development of
18	Q. For this statement, were you	18	complications, right?
19	including literature on rates of removal from both	19	A. On exact mechanisms? No.
20	hernia repair and transvaginal mesh repairs?	20	Q. There is no conflict of interest
21	A. It was pertinent to both. So I	21	disclosure in Exhibit 1201 for you, is there?
22	don't remember exactly if 10 percent was for hernia	22	MR. ORENT: Objection. Asked and
23	or transvaginal. I suspect it could have been for	23	answered.
24	transvaginal from what I remember.	24	THE WITNESS: The same thing. During
25	Q. You write:	25	submission there was an option, if there was an
	Page 211		Page 213
1	"We studied 103 explanted	1	option, submitted all information I could during
2	meshes and different designs,	2	presentations. If it's PowerPoint presentation,
3	manufacturers and anatomical sites	3	the first slide which appears after the title slide
		-	the first sinde which appears after the title sinde
4	using conventional and transmission	4	is disclosure of conflict.
4 5	using conventional and transmission electron microscopy."		**
	-	4	is disclosure of conflict.
5	electron microscopy."	4 5	is disclosure of conflict. BY MS. BYARD:
5 6	electron microscopy." Correct?	4 5 6	is disclosure of conflict. BY MS. BYARD: Q. A conflict of interest disclosure
5 6 7	electron microscopy." Correct? A. That's correct.	4 5 6 7	is disclosure of conflict. BY MS. BYARD: Q. A conflict of interest disclosure does not appear in Exhibit 1201, does it?
5 6 7 8	electron microscopy." Correct? A. That's correct. Q. Why are we at 103 here, compared	4 5 6 7 8	is disclosure of conflict. BY MS. BYARD: Q. A conflict of interest disclosure does not appear in Exhibit 1201, does it? MR. ORENT: Objection.
5 6 7 8 9	electron microscopy." Correct? A. That's correct. Q. Why are we at 103 here, compared to the sample size of 120 we saw in Exhibit 1200?	4 5 6 7 8 9	is disclosure of conflict. BY MS. BYARD: Q. A conflict of interest disclosure does not appear in Exhibit 1201, does it? MR. ORENT: Objection. THE WITNESS: It's up to a journal.
5 6 7 8 9	electron microscopy." Correct? A. That's correct. Q. Why are we at 103 here, compared to the sample size of 120 we saw in Exhibit 1200? A. Multiple reasons. It could be	4 5 6 7 8 9	is disclosure of conflict. BY MS. BYARD: Q. A conflict of interest disclosure does not appear in Exhibit 1201, does it? MR. ORENT: Objection. THE WITNESS: It's up to a journal. BY MS. BYARD:
5 6 7 8 9 10 11	electron microscopy." Correct? A. That's correct. Q. Why are we at 103 here, compared to the sample size of 120 we saw in Exhibit 1200? A. Multiple reasons. It could be different point in time when this abstract was	4 5 6 7 8 9 10	is disclosure of conflict. BY MS. BYARD: Q. A conflict of interest disclosure does not appear in Exhibit 1201, does it? MR. ORENT: Objection. THE WITNESS: It's up to a journal. BY MS. BYARD: Q. Is there a conflict of interest
5 6 7 8 9 10 11 12	electron microscopy." Correct? A. That's correct. Q. Why are we at 103 here, compared to the sample size of 120 we saw in Exhibit 1200? A. Multiple reasons. It could be different point in time when this abstract was written. Something else, like not completed study	4 5 6 7 8 9 10 11	is disclosure of conflict. BY MS. BYARD: Q. A conflict of interest disclosure does not appear in Exhibit 1201, does it? MR. ORENT: Objection. THE WITNESS: It's up to a journal. BY MS. BYARD: Q. Is there a conflict of interest disclosure that appears in Exhibit 1201, sir?
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5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	electron microscopy." Correct? A. That's correct. Q. Why are we at 103 here, compared to the sample size of 120 we saw in Exhibit 1200? A. Multiple reasons. It could be different point in time when this abstract was written. Something else, like not completed study at that time, because I would need polarize or measure the degradation thickness; so I don't know. But at that time when the abstract was written, total number was 103. Q. You conclude this abstract by writing: "The discovery" and you're referring to the discovery of degradation under microscopy " opens the door to study the role	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	is disclosure of conflict. BY MS. BYARD: Q. A conflict of interest disclosure does not appear in Exhibit 1201, does it? MR. ORENT: Objection. THE WITNESS: It's up to a journal. BY MS. BYARD: Q. Is there a conflict of interest disclosure that appears in Exhibit 1201, sir? MR. ORENT: Objection. THE WITNESS: I don't see it. Maybe it was somewhere at the end of the journal issue, I don't know. I mean, this is just a page from the issue. Maybe they had conflict of interest gathered at the end. BY MS. BYARD: Q. I'd like to turn back to your report, which is Exhibit 1196. Are you on the "Opinion" section with
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	electron microscopy." Correct? A. That's correct. Q. Why are we at 103 here, compared to the sample size of 120 we saw in Exhibit 1200? A. Multiple reasons. It could be different point in time when this abstract was written. Something else, like not completed study at that time, because I would need polarize or measure the degradation thickness; so I don't know. But at that time when the abstract was written, total number was 103. Q. You conclude this abstract by writing: "The discovery" and you're referring to the discovery of degradation under microscopy	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	is disclosure of conflict. BY MS. BYARD: Q. A conflict of interest disclosure does not appear in Exhibit 1201, does it? MR. ORENT: Objection. THE WITNESS: It's up to a journal. BY MS. BYARD: Q. Is there a conflict of interest disclosure that appears in Exhibit 1201, sir? MR. ORENT: Objection. THE WITNESS: I don't see it. Maybe it was somewhere at the end of the journal issue, I don't know. I mean, this is just a page from the issue. Maybe they had conflict of interest gathered at the end. BY MS. BYARD: Q. I'd like to turn back to your report, which is Exhibit 1196. Are you on the "Opinion" section with me, sir?
5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	electron microscopy." Correct? A. That's correct. Q. Why are we at 103 here, compared to the sample size of 120 we saw in Exhibit 1200? A. Multiple reasons. It could be different point in time when this abstract was written. Something else, like not completed study at that time, because I would need polarize or measure the degradation thickness; so I don't know. But at that time when the abstract was written, total number was 103. Q. You conclude this abstract by writing: "The discovery" and you're referring to the discovery of degradation under microscopy " opens the door to study the role of degradation in the development of	4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	is disclosure of conflict. BY MS. BYARD: Q. A conflict of interest disclosure does not appear in Exhibit 1201, does it? MR. ORENT: Objection. THE WITNESS: It's up to a journal. BY MS. BYARD: Q. Is there a conflict of interest disclosure that appears in Exhibit 1201, sir? MR. ORENT: Objection. THE WITNESS: I don't see it. Maybe it was somewhere at the end of the journal issue, I don't know. I mean, this is just a page from the issue. Maybe they had conflict of interest gathered at the end. BY MS. BYARD: Q. I'd like to turn back to your report, which is Exhibit 1196. Are you on the "Opinion" section with

54 (Pages 210 to 213)

Page 214 Page 216 1 "Explanted mesh specimens show 1 A. Yes. They are important to 2 non-specific reaction of the body to 2 understand. I mean, everything is important to my 3 a foreign object, as well as findings 3 opinion, because I wouldn't be providing this opinion if I didn't go to medical school. So you 4 specific for a mesh type or an 4 5 5 have to go back to 1986. anatomical location." Is that right? 6 Q. I don't think we have time for 6 7 7 A. That's correct. that, unfortunately. 8 O. You continue: 8 Under paragraph 2 of your opinions, 9 "Findings for abdominal mesh 9 there's a sentence that reads: 10 explants differ from findings for 10 "This reaction --" and you're 11 vaginal mesh implants." 11 talking about the foreign body reaction "-- persists until the 12 A. That's correct. 12 13 O. How so? 13 inciting agent is either removed, in 14 parenthesis, [expelled or reabsorbed]." 14 A. I've explained some of the 15 differences earlier. Hernia meshes are placed in 15 Are you with me? 16 parallel to anatomical planes. There are 16 A. "Resorbed". separated, well defined planes between fascia, 17 17 Q. Resorbed. Thank you. adipose tissue, muscle and transvaginal 18 Does there come a point in time, in the 18 tissue response to mesh, where the inflammatory 19 allocations. There is no fascia, really, there's 19 response reaches a chronic or steady state? 20 no anatomical plane. The tissue gradually 20 21 transitions into -- one to another. 21 A. Foreign body reaction is a chronic 22 Another difference is that functionally, 22 inflammatory reaction. 23 23 When it starts, it may start acutely abdominal wall is just holding pressure of --24 abdominal pressure. While vaginal tissue has 24 but on its own it's a chronic response. Not may 25 completely different purpose. There is more 25 start; it starts acutely after the placement of Page 215 Page 217 mobility, there is stress of bladder expansion, foreign body, and then continues on as a chronic 1 1 2 2 bowel movement, then stress of intercourse. response. 3 Muscles within the bladder wall, 3 Q. Does the foreign body response 4 muscles within the vaginal wall which contract, 4 drop off over time? 5 type of innervation is completely different. 5 A. Not in what I see. In relation to 6 6 polypropylene, I see even -- I think my oldest Where in the abdominal wall, it mainly 7 7 serves as a passage of nerves parallel to abdominal specimen was 12 years after insertion, and I still 8 wall, where the vagina is practically the target of 8 see inflammatory -- chronic body -- chronic foreign 9 innervation, because the endings are there, and the 9 body type reaction. 10 nerves are in different orientation. 10 So in relation to polypropylene, it's a 11 variable. But I've never seen it went away 11 And I can continue on and on, I mean 12 it's -- abdominal wall is a completely sealed 12 completely. 13 environment, there's no contamination. Vaginal 13 Q. Does the foreign body reaction drop off after this acute phase that you've 14 environment is contaminated. Do you want me to 14 described? And I don't mean completely, but just 15 continue? 15 16 O. Are those the main differences 16 decrease? 17 17 A. That was one of the questions. that you're noting? And I would expect that it would decrease, but so 18 A. I mean --18 19 19 far have not been able to show it. Every time I'm Q. Those are the ones that are 20 important to your opinions here? 20 checking, every time data builds up and then I 21 21 A. I can continue more with the check if there is correlation between foreign body 22 differences. 22 reaction, what degree, and I'm just -- it doesn't 23 Q. Are they relevant to your opinions 23 correlate yet. 24 in this report, the other differences besides those 24 Maybe I need to go to a thousand cases 25 and then I see some weak correlation. What seems 25 that you've mentioned?

	Page 218		Page 220
1	to be a case that it's variable between	1	that was. I mean, I just don't remember now.
2	individuals, or maybe it's variable within the same	2	Q. Okay. And that's fine. And I
3	individual, so it fluctuates with time. But again,	3	think your testimony in response to my question
4	that's why we need to study all this.	4	about how many sutures are placed, for example,
5	Q. So those conclusions haven't been	5	during abdominal paravaginal repair, is that you
6	established yet, based on your observations to	6	don't know for certain that the amount of materials
7	date?	7	are less than with the surgical mesh; is that fair?
8	MR. ORENT: Objection.	8	A. Significantly less, that is fair.
9	THE WITNESS: What exactly defines the	9	Q. You write in paragraph 4 of your
10	degree of foreign body reaction? No, the degree is	10	opinions, and I'm just reading part of the sentence
11	not.	11	that I want to ask you about is that:
12	I mean, we know	12	"The filaments" here you're
13	BY MS. BYARD:	13	referring to vaginal mesh " are
14	Q. The degree and I guess what I'm	14	always surrounded by fibrous scar."
15	focusing on is, it's activity over time?	15	Do you see that?
16	A. Yes. This is not completely	16	A. Yes.
17	understood. What we know, it is present and it is	17	Q. Is it true that you see tissue
18	always present.	18	changes to mesh adjacent to the mesh, but at some
19	Q. Okay.	19	point you see a resumption in normal tissue
20	A. In all specimens.	20	response?
21	Q. You write here in your third	21	A. What do you mean, "resumption of
22	paragraph that:	22	normal tissue response?"
23	"A mesh is a large foreign body	23	Q. So you see a foreign body reaction
24	in comparison to regular surgical	24	and chronic inflammatory state in the tissue
25	sutures." Right?	25	immediately adjacent to the mesh, correct?
			, <u>-</u>
	Page 219		Page 221
1	Page 219 A. That's correct.	1	Page 221 A. That's correct.
1 2		1 2	
	A. That's correct.		A. That's correct.
2	A. That's correct.Q. Do you note how many surgical	2	A. That's correct.Q. But at some point and distance
2 3	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal	2 3	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to
2 3 4	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs?	2 3 4	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct?
2 3 4 5	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every	2 3 4 5	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue
2 3 4 5 6	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller	2 3 4 5 6	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond;
2 3 4 5 6 7	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be.	2 3 4 5 6 7	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal.
2 3 4 5 6 7 8	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance	2 3 4 5 6 7 8	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal. Q. Okay.
2 3 4 5 6 7 8	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance of an abdominal paravaginal repair?	2 3 4 5 6 7 8	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal. Q. Okay. A. So
2 3 4 5 6 7 8 9	A. That's correct. Q. Do you note how many surgical sutures are used, for example, in abdominal paravaginal repairs? A. They're not placed every millimeter or so, that's for sure. Much smaller amount than a mesh would be. Q. Have you ever seen the performance of an abdominal paravaginal repair? A. I've seen some surgeries, I	2 3 4 5 6 7 8 9	A. That's correct. Q. But at some point and distance away from the mesh, you see the body return to normal tissue responses, correct? A. There is no response. Tissue response is abnormal tissue, which doesn't respond; that's normal. Q. Okay. A. So Q. So then maybe if we can
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	Page 222		Page 224
1	Q. Have you measured to find a range	1	THE WITNESS: Thank you.
2	at which the average return to normal tissue is	2	THE VIDEOGRAPHER: Off the record at
3	from the mesh?	3	2:44 p.m.
4	A. I don't think you're using words	4	RECESS AT 2:44
5	"return" is not	5	UPON RESUMING AT 4:35
6	Q. Okay.	6	THE VIDEOGRAPHER: We're back on the
7	A. It's not applicable. You don't	7	record at 4:37 p.m.
8	know if it was scar and then return actually,	8	BY MS. BYARD:
9	it's impossible.	9	Q. Doctor, attached to your report
10	Q. Okay. So is there, I guess and	10	are a number of figures numbered 1 through 20,
11	help me with how to phrase it. But is there a	11	correct?
12	distance have you measured let's start over.	12	A. Figure sets, I believe, sometimes
13	Have you measured how far away from the	13	they are gathered in sets.
14	mesh the tissue ordinarily appears normal?	14	Q. Sitting here today, is it true
15	A. Yes. I didn't perform statistical	15	that you are not able to tell me what clinical
16	analysis or study, but I measured approximately	16	complications or symptoms led to each of these
17	what's the distance of changes.	17	patients whose specimens are depicted in Figures 1
18	Q. And what is that distance on	18	through 20? Wait, let me start over, I don't think
19	average?	19	I finished that right. Strike that.
20	A. It's within one to two millimeters,	20	Now, is it true that sitting here
21	not greater than two, at least from most of the	21	today, you're not able to tell me that clinical
22	cases I see.	22	symptoms leading to these excision surgeries of
23	Q. So in most instances, when looking	23	each of the patients whose specimens are depicted
24	at a transvaginal mesh and tissue specimen, you	24	in Figures 1 through 20?
25	will see normal tissue one to two millimeters from	25	A. You mean, do I remember the
	Page 223		Page 225
1	the mesh?	1	history for a specific photograph and
2	A. Yeah. From the most, outermost	2	Q. (Nods).
3	point of mesh filament. Usually it's within one to	3	A. I don't. Is it what you meant?
4	two or I would say, to be safe, one to three	4	Q. Yes, that was what I meant. Thank
5	millimeters. I don't see it exceeding three	5	you.
6	millimeters, unless there is something else, like	6	A. I don't remember histories, I
7	an abscess.	7	mean, they are all collected from Boston Scientific
8	If there's an abscess, then there is	8	or most of them. If it's not, they are specified
9	much more scarring in the area. Or, if there is	9	to be a known Boston Scientific.
10	erosion, there's inflammation, there is much more	10	Q. Okay. And so similarly, you
11	damage to the tissue, then it expands.	11	aren't able to tell me that for the figures
12	But if we go into deep environment and	12	numbered 1 through 20, when any symptoms began,
13	changes which can be only attributed to mesh, then	13	that led to the excisions resulting in the
14	it's within three millimeters beyond the mesh.	14	specimens whose that are depicted in Figures 1
15	But, if the mesh is curled, or folded	15	through 20, right?
16	like POP, the distance between two mesh planes in	16	MR. ORENT: Objection.
17	the fold can be much greater, five, six millimeters,	17	THE WITNESS: When specific symptoms
18	and this will all be filled by scar. I'm talking	18	began?
19	about extent towards normal tissue.	19	BY MS. BYARD:
20	Q. That's what I was asking.	20	Q. (Nods.)
	A. Externally, yes.	21	A. No, I cannot.
21		1	0 01 11 1 12
21 22	Q. Okay. Good.	22	Q. Okay. Thank you, Doctor.
	Q. Okay. Good.MS. BYARD: Doctor, I want to keep you	22	Q. Okay. Thank you, Doctor. Returning to your report and
22		1	The state of the s

	Page 226		Page 228
1	A. Yes.	1	ahead.
2	Q. I just want to look at one	2	THE WITNESS: We have to kind of
3	sentence there at the end, where you write that:	3	separate it, other clinical publications saying
4	""Mature scar tissue after	4	that mesh non-mesh surgeries are free of
5	non-mesh surgeries "the sentence	5	complications?
6	continues " can remodel with time."	6	No. Because any surgery has a form of
7	Can you see that?	7	complication early complications, or later
8	A. Yes, I do.	8	complications. I mean, it depends what surgery. I
9	Q. Is it your opinion that scar	9	mean, then again, it's so broad and kind of worded
10	tissue from mesh surgeries can't remodel with time?	10	in
11	A. Cannot or can?	11	BY MS. BYARD:
12	O. Cannot.	12	Q. Okay, sure. And I just wanted to
13	A. It can. It can remodel, but the	13	see if we could agree that non-mesh surgeries can
14	mesh cannot remodel.	14	also result in long-term clinical complications?
15	Q. So the scar tissue I'm sorry.	15	MR. ORENT: Objection.
16	A. So there will always be scar	16	THE WITNESS: Which I mean, any
17	around the mesh. If mesh travels, migrates, the	17	surgery will have specific complications. Early or
18	scar will remodel.	18	later, we have to take specific surgery and then
19	So does that answer your question?	19	compare. Non-mesh surgery will not have long-term
20	Q. Yes, it does.	20	complications of meshes; that's clear.
21	So you would agree with me that scar	21	If there is no mesh, there will not be
22	tissue surrounding mesh can remodel over time?	22	complications related to the mesh. If there is
23	A. Yes, it can.	23	mesh, there can be complications related to the
24	Q. Okay. The sentence continues that:	24	mesh.
25	"Mature scar tissue from	25	mesn.
	TANGE STATE VISCOUT FROM		
	Page 227		Page 229
1			
1	non-mesh surgeries does not exhibit	1	BY MS. BYARD:
2	non-mesh surgeries does not exhibit the same long-term reactions or	1 2	BY MS. BYARD: Q. So you can't cite for me, can you,
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2		2	
2	the same long-term reactions or clinical complications".	2 3	Q. So you can't cite for me, can you, what the rate of pain with a non-mesh
2 3 4	the same long-term reactions or clinical complications". Do you see that?	2 3 4	Q. So you can't cite for me, can you, what the rate of pain with a non-mesh perineorrhaphy is compared to a posterior repair
2 3 4 5	the same long-term reactions or clinical complications". Do you see that? A. That's correct.	2 3 4 5	Q. So you can't cite for me, can you, what the rate of pain with a non-mesh perineorrhaphy is compared to a posterior repair with mesh; can you?
2 3 4 5 6	the same long-term reactions or clinical complications". Do you see that? A. That's correct. Q. I just want to focus on the term	2 3 4 5 6	Q. So you can't cite for me, can you, what the rate of pain with a non-mesh perineorrhaphy is compared to a posterior repair with mesh; can you? MR. ORENT: Objection. Outside the
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Page 230 Page 232 1 A. No, this is not correct. You're 1 that it's polypropylene. So these would be 2 mixing up things. So let's split it. 2 findings in light microscope. And if we go to 3 If you want me to explain, I will 3 transmission electron microscopy, I can see 4 explain. If you want me to answer your question, I 4 transition. I see non-degraded, sort of finely 5 will; what do you want? 5 granule, almost smooth, no granulation, sort of 6 Q. Okay. Well, you have three -- you granularity. And then there's a smooth transition 7 have three basic findings. 7 into smaller cracks, fine lattice of cracks, and 8 A. No, no, not three. There are way 8 then it expands, and expands, and expands in larger 9 more than three, but... 9 crevices towards the surface. 10 MR. ORENT: Just let her --10 So there's a range of degradation from 11 THE WITNESS: Okay. a core to the surface. So this findings would 11 12 BY MS. BYARD: 12 confirm that this is -- this stainable layer is in 13 Q. Is it your opinion that 13 fact polypropylene. 14 polypropylene mesh degrades in vivo, in part 14 Q. Okay. So then what was wrong with 15 because the degraded bark is able to trap 15 my question --16 histological dyes? 16 MR. ORENT: Wait, hold on. He's not 17 A. No, this is not correct. 17 done. 18 Q. Explain it to me then. 18 THE WITNESS: Then there's a next set 19 A. So let's dissect it. 19 of findings, which is proving that it is altered or 20 So first, what findings in the light 20 degraded polypropylene. 21 microscope and electron transmission microscope 21 All right. First, we concluded that it 22 through cross-sections prove that the layer I 22 is polypropylene. And the second set of findings 23 observe is polypropylene? 23 proving that it's altered polypropylene. 24 So the first finding, light microscopy, 24 Obviously, first thing which is visible 25 it polarizes. So it behaves as polypropylene --25 in light microscopy is it observes dye. Page 231 Page 233 1 non-degraded polypropylene in polarized light. So 1 Non-degraded polypropylene is completely clear, 2 2 this is first finding. it's solid, it doesn't have pores to trap dyes. 3 Second finding is that those mesh 3 The degraded polypropylene absorbs 4 filaments where there are blue granules included, I 4 dyes. And, if I do staining with two stains, one 5 observed them in this stainable layer. So this is is with small molecular size of the dye, and one is 6 6 larger molecular size of the dye. The smaller another proof that it's coming from polypropylene. 7 7 Then with other stains, as for one molecule -- the dye with smaller molecule size will 8 8 retain in smaller cracks, really fine sort of cause of stain, because the stainable layer is 9 9 brittle, it cracks. So the first question for microcracks. And then larger molecules would stay 10 pathologists would be, can it be calcified 10 in the larger. material? Which is very common to have calcified 11 11 So, therefore, I had this trichrome 12 12 material in human body, especially with long-term stain layer of red, which indicates smaller 13 chronic processes. So I did Von Kossa stain, 13 porosity we see in the degraded material, and then 14 14 calcium stain, it's not -- it's not staining for a layer of green color, which highlights a larger 15 15 calcium. porosity material. So this is degraded in light microscopy. 16 The next set of stains was to stain for 16 17 proteins, because if it's a protein, it mixes, it's 17 Cracking, that's another feature. 18 18 a hydrophilic mix of some sort, to mix with Peeling off. So what happens, there is internal 19 19 proteins. So I stained it for several force -- it's like drying, it's like drying on lips 20 ubiquitous -- "ubiquitous" means present in many 20 or like rust on the surface of the metal. Because 21 body fluids, immunoglobins, and it doesn't stain 21 it shrinks somewhat, and then the internal force 22 the layer. It's deposited right next to it, it 22 pulls it, there's a crack, but it pulls and sloughs 23 goes into crevices, it follows the surface, but it 23 off of non-degraded surface, and then it starts 24 doesn't mix. Again, this shows that the material 24 peeling.

59 (Pages 230 to 233)

So that's another feature showing that

25

25

is hydrophobic, and doesn't mix again; proof is

Page 236 Page 234 1 because it's dead then, they get stuck. So this is it's degrading, it's changing properties, physical 1 properties and it's non-degraded material. 2 2 another process. Degraded material was present in 3 BY MS. BYARD: 3 vivo, while the inflammatory cells were mobile, so 4 they could do that. So that's kind of overview. Q. Okay. 4 5 A. And then there is a third set of 5 Q. And maybe we're talking past each 6 6 other. What I was focusing on was paragraph 6. findings, which proves that it happens in vivo. So "in vivo" means that it happens before it is --7 7 And there you list its ability to trap histological dyes, right? 8 Q. Explanted? 8 9 A. Piece of mesh is excised. So one 9 A. That's proof that it's altered. 10 10 Q. There you also list that it of the findings is that some surgeries are done with electric cautery devices. So the edges of the 11 retains inclusions of blue granules? 11 12 A. That's proof that it was protein, 12 specimen are burned, and it melts polypropylene. So this sides, I can see that the degraded material 13 that it's originating from original protein. Not 13 14 protein, I'm sorry. Polypropylene. That it 14 melted, and non-degraded material melted. And then 15 they melt together and form one pool, and they 15 originates from polypropylene, which was 16 16 manufactured with inclusion of blue granules. merge together and crystalize together. 17 17 Q. And then you list optical So this also shows that it is 18 properties in polarized light, right? 18 polypropylene, because in melted state, they're 19 A. Yes. Which are very different 19 compatible. So they can recrystallize on their own. 20 from anything else in the body, and this shows as 20 But, it also indicates that the tool 21 21 was touching it when it was already present. So it well that it's polypropylene. 22 Q. Okay. So those were the three 22 means that it was forming in vivo, before it was 23 buckets I was talking about that were listed there 23 burned. 24 in paragraph 6. 24 Another feature shows that it was in 25 A. Yup. But then there is a 25 vivo, is when I measure degradation layer and Page 235 Page 237 1 correlated it with time, it was gradually growing 1 description in the pictures with figure captions 2 further going into the details. over the years. So the first time when you can see 2 3 it with light microscope, is probably about a year 3 Q. Okay. I understand that. 4 or two in vivo. And then there is a rapid growth 4 Have you just described for me all of 5 5 which later on plateaus and goes really slow, which the findings that you've made that lead you to 6 6 conclude that polypropylene degrades in vivo? is biological response. I mean, it grows to a 7 7 specific thickness, and then the rate of growth A. I think most. 8 8 slows down. So this also proves that it forms in Q. I think so. 9 vivo. 9 Can you identify for me, any 10 Another thing I said, I put new meshes 10 peer-reviewed published literature, besides your 11 in formalin, and kept them in formalin up to four 11 own that we've looked at, that describe these three 12 months, and then kept them -- and put them for 12 findings that are set forth in paragraph 6? 13 processing and examined them. There's no 13 A. Okay. So you have to remind me 14 degradation bark after four months. So, expose it 14 which three findings; the blue granules? 15 15 to formalin up to four months, it doesn't form Q. Blue granules, ability to track 16 degradation. Again, if degradation is present and 16 histological dyes, and optical properties in 17 formalin doesn't cause it, it was present before 17 polarized light? A. Blue granules, no. Polarized 18 surgery. 18 19 19 light has been used to identify foreign materials And then for transmission electron 20 microscopy, the fact that inflammatory cells could 20 for decades. 21 21 migrate partially in the cracks, into crevices and Q. Okay. But not degradation? 22 expand, that's what they normally do, inflammatory 22 A. Including degradation. 23 cells go through very tight spots to migrate 23 Q. Of polypropylene? 24 through the vessel walls. They try to do the same 24 A. Not poly -- well, polypropylene 25 thing into the cracks of degraded material, but 25 is, no; because sutures were around. So what

	Page 238		Page 240
1	pathologists do, they see something, it's clear,	1	THE WITNESS: Specifically for
2	it's not sure if it's foreign or a native tissue,	2	polypropylene, yes, I'm the first one.
3	polarize and see what's the state of it.	3	BY MS. BYARD:
4	Specifically for degradation bark, the	4	Q. Let's talk a little bit about how
5	way I describe it, no. But, I mean, generally,	5	specimens get to you from the surgical location,
6	pathologists identify foreign bodies, including	6	all right? In order to understand it and breakdown
7	polypropylene sutures, and they assess the state	7	what you've said here in paragraph 6 a little bit
8	they are in.	8	better.
9	Q. My question is more narrow than	9	You would agree with me that all the
10	what you're responding to, okay?	10	specimens that you've reviewed were excised during
11	My question is simply whether there is	11	surgery by a physician, right?
12	peer-reviewed published literature besides your own	12	A. That's correct.
13	that we've looked at, that describes finding of	13	Q. And apart from what's described in
14	degradation of polypropylene with polarized light?	14	the operative report of the excision, you don't
15	MR. ORENT: Objection. Misstates the	15	know beyond that, what was done to remove the mesh,
16	opinions of Dr. Iakovlev.	16	correct?
17	THE WITNESS: As I said, the state of	17	A. Specific details, no. The only
18	polypropylene sutures and the examination in	18	thing I need to assess as a pathologist, is
19	polarized light has been described before. Nobody	19	acceptable for examination and to what degree I can
20	coined it as I did as a bark, and went into these	20	examine it.
21	details, that's true.	21	Q. Okay. And my question is a little
22	But, was it used to see if	22	different.
23	polypropylene is there and if it's in degraded	23	My question is, beyond what's set forth
24	state or yes.	24	in the op report describing this excision
25	,	25	procedure, you don't know the details of what the
	Page 239		Page 241
1	Page 239 BY MS. BYARD:	1	Page 241 surgeon did to remove that specimen, correct?
1 2		1 2	
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61 (Pages 238 to 241)

	Page 242		Page 244
1	BY MS. BYARD:	1	and piecemeal not necrose sorry, I'm a little
2	Q. For instance, are you able to	2	bit.
3	discern whether the doctor used a scalpel or	3	If it's piecemealed resection and it's
4	Metzenbaum scissors?	4	raggedy, it's clear that it was difficult excision.
5	A. It doesn't matter to me. I mean,	5	If it's cleanly excised, no damage to it, I mean,
6	this is completely irrelevant.	6	it's clear that it was easy excision.
7	Q. Okay. So the answer to my	7	Q. In the litigation context, you
8	question is, no, you're not able to discern that,	8	don't review the depositions of the excising
9	right?	9	surgeons, right?
10	A. No, I don't know why you're asking	10	A. No.
11	me this.	11	Q. You don't speak to the excising
12	Q. Doctor, I just I just am asking	12	surgeons in the litigation context, do you?
13	you my questions. If you understand where they're	13	A. No.
14	coming from or not, is okay. But I just need	14	Q. Generally, though, you do know
15	answers so that we can move along, all right?	15	that doctors when excising specimens, need to grip
16	A. Okay.	16	the area of mesh that they're removing in order to
17	Q. Okay. So the answer to my	17	accomplish the surgery, right?
18	question is that you can't discern whether scalpel	18	A. Of course.
19	or scissors were used, for example?	19	Q. And unless it's set forth in the
20	MR. ORENT: Objection.	20	operative report, you don't know what
21	THE WITNESS: I can discern if it was	21	instrumentation was used to grip the mesh, correct?
22	hot or cold instrument.	22	A. No.
23	BY MS. BYARD:	23	Q. Similarly, to the extent that
24	Q. Okay, thank you.	24	distortions to the mesh occur as the doctor is
25	A. Or if it was crushing or sharp,	25	cutting and removing it, you're not able to tell
	Page 243		Page 245
1	that I can discern, but not beyond that.	1	whether that distortion occurred in vivo, or
2	Q. Thank you. And again, apart from	2	whether it occurred during this removal process,
3	what's set out in the operative report, you can't	3	correct?
4	identify what degree of force, if any, was used to	4	A. That is not correct.
5	excise the specimen, correct?	5	Q. For example, if you are given two
6	MR. ORENT: Objection.	6	specimens of mesh from a sling incision, you
7	THE WITNESS: I can only define the	7	couldn't say that the mesh was broken apart in the
8	degree of manipulation instrument or other handling	8	women's body before it was removed, right?
9	affected it to a degree where I cannot assess if	9	A. This is not correct.
10	it's acceptable or not; that's what I can assess.	10	MR. ORENT: Objection.
11	If the degree of manipulation was not	11	THE WITNESS: Again, this is the second
12	strong enough to alter it in the way it would	12	incorrect statement.
13	change microscopic appearance, then I cannot. But	13	BY MS. BYARD:
14	then it becomes irrelevant, because it doesn't	14	Q. Is the way that you would tell,
15	affect my ability to interpret it.	15	based on whether the both specimens are
		1 10	
16	BY MS. BYARD:	16	encapsulated in scar tissue?
16 17	Q. And perhaps we can come back to	17	A. There are multiple other features
17 18	Q. And perhaps we can come back to that in reference to some of the specific cases	17 18	A. There are multiple other features they can see. If damage was in the body, white
17	Q. And perhaps we can come back to that in reference to some of the specific cases tomorrow. But I'll move on for now.	17 18 19	A. There are multiple other features they can see. If damage was in the body, white cell reaction, I mean, including scar
17 18	Q. And perhaps we can come back to that in reference to some of the specific cases	17 18	A. There are multiple other features they can see. If damage was in the body, white
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17 18 19 20	Q. And perhaps we can come back to that in reference to some of the specific cases tomorrow. But I'll move on for now. On a similar line of questioning, you	17 18 19 20	A. There are multiple other features they can see. If damage was in the body, white cell reaction, I mean, including scar encapsulation, your guess was right.
17 18 19 20 21	Q. And perhaps we can come back to that in reference to some of the specific cases tomorrow. But I'll move on for now. On a similar line of questioning, you don't typically know, unless it's set forth in the	17 18 19 20 21	A. There are multiple other features they can see. If damage was in the body, white cell reaction, I mean, including scar encapsulation, your guess was right. Q. So after excision, the specimen is
17 18 19 20 21 22	Q. And perhaps we can come back to that in reference to some of the specific cases tomorrow. But I'll move on for now. On a similar line of questioning, you don't typically know, unless it's set forth in the operative report, what degree of difficulty the	17 18 19 20 21 22	A. There are multiple other features they can see. If damage was in the body, white cell reaction, I mean, including scar encapsulation, your guess was right. Q. So after excision, the specimen is sent to pathology and put in a jar of formalin?

1	Page 246		Page 248
_	Q. And I think you said the longest	1	operating room to the laboratory?
2	that you put your control sample of virgin mesh in	2	A. After grossing. After I gross or
3	a jar of formalin was four months?	3	somebody gross the specimen, they take sections, so
4	A. Up to four months, yes.	4	it could fit in the cassettes. Then the cassettes
5	Q. So from the operating room, the	5	are loaded in the machine, and then there's a
6	specimen goes to pathology at the patient's	6	process of dehydration, saturation of tissue with
7	hospital or a local hospital typically, correct?	7	paraffin, and then the tissue can be cut when
8	A. That's correct.	8	paraffin solidifies and then it can be cut.
9	Um, if it is preserved, it goes to a	9	Q. Sometimes that dehydration and
10	lab through some channels. Some specimens are not	10	alcohol application and saturation with paraffin
11	preserved, they are discarded.	11	process happens in your laboratory for these
12	Q. If the sample or specimen is	12	litigation specimens, but sometimes they happen at
13	examined by a local pathologist, it's examined	13	the local hospital?
14	grossly and/or microscopically, typically, right?	14	A. That's correct.
15	A. There should be some form of	15	Q. How long does the process of
16	examination, gross or microscopic; yes, that is	16	applying increasing alcohol concentrations take?
17	correct.	17	A. The machine can be programmed
18	Q. Okay. You talked about the sample	18	differently, but roughly it runs about, the full
19	being preserved; what does that process entail?	19	cycle is anywhere between 12 to 24 hours, with
20	A. The main preservative is formalin,	20	different solutions. The short
21	so it's kept in formalin.	21	Q. Is it just alcohol?
22	Q. For the litigation context, you	22	A. No, no. There are serial
23	received samples through a company called	23	concentrations of alcohol increasing, and then
24	Steelgate, right?	24	xylene, and then xylene is replaced by paraffin.
25	A. Most of the samples came through	25	MR. ORENT: "Saline"?
23	71. Wost of the samples came through	23	MR. OKLAT. Same :
	Page 247		Page 249
1	Steelgate, sometimes it comes from law firms	1	BY MS. BYARD:
2	directly or through Scisafe.	2	Q. X-Y-L-E-N-E?
3	Q. Spell that for me.	3	A. That's correct.
4	A. I think it is Scisafe. S-C-I	4	Q. Then paraffin?
5	safe. My understanding is, it is a company similar	1	Q. Then paranin?
	saic. My understanding is, it is a company similar	5	*
6		5 6	A. And all of those new meshes went
6 7	to Steelgate.		A. And all of those new meshes went through all the same steps, they were loaded in the
7	to Steelgate. Q. So someone has, either Steelgate	6	A. And all of those new meshes went through all the same steps, they were loaded in the same machine.
	to Steelgate. Q. So someone has, either Steelgate or Scisafe of a Plaintiffs' firm, sent those	6 7	A. And all of those new meshes went through all the same steps, they were loaded in the same machine. Q. You anticipated my question.
7 8 9	to Steelgate. Q. So someone has, either Steelgate or Scisafe of a Plaintiffs' firm, sent those specimens to you at this point in the process from	6 7 8	A. And all of those new meshes went through all the same steps, they were loaded in the same machine. Q. You anticipated my question. So the virgin mesh that you examined
7 8 9 10	to Steelgate. Q. So someone has, either Steelgate or Scisafe of a Plaintiffs' firm, sent those specimens to you at this point in the process from the operating room to your lab?	6 7 8 9 10	A. And all of those new meshes went through all the same steps, they were loaded in the same machine. Q. You anticipated my question. So the virgin mesh that you examined for degradation went through this alcohol
7 8 9	to Steelgate. Q. So someone has, either Steelgate or Scisafe of a Plaintiffs' firm, sent those specimens to you at this point in the process from the operating room to your lab? MR. ORENT: Objection.	6 7 8 9	A. And all of those new meshes went through all the same steps, they were loaded in the same machine. Q. You anticipated my question. So the virgin mesh that you examined for degradation went through this alcohol dehydration?
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	Page 250		Page 252
1	thickness of the degradation layer; there was no	1	immunoperoxidase stains to do the S100 nerve
2	correlation between the storage time. It showed 0	2	observations?
3	correlation. It was exactly like minus 0.06 or	3	A. Yes. Immunoperoxidase stain is
4	something like this.	4	technique for immunostains where antibodies labeled
5	While the correlation between in vivo	5	against specific proteins. And then you choose
6	and thickness of the bark was .76 which is very	6	antibody against what protein you want to stain.
7	good for biological response.	7	Q. You describe in your study with
8	Q. Is this data somewhere where I	8	Dr. Carey, enzyme digestion for four minutes; what
9	could look at it?	9	is that, for a lay person?
10	A. The publication is almost	10	A. It's the way you try to reverse
11	published. I mean, it's ready, it's written, so I	11	affect of formalin on tissue. So how formalin
12	need to just submit it. And, hopefully, when it is	12	preserves tissue, it crosslinks proteins in a way
13	submitted soon, and it will be accepted, then I can	13	that bacteria cannot degrade it anymore.
14	present it to you.	14	It's crosslinked, it ties up in a way
15	Q. And until it's published, you	15	that bacteria cannot digest it. But then some of
16	wouldn't share that because it's considered	16	the epitopes, it points where antibody is
17	confidential by you at this point	17	connecting, are hidden in this sort of crosslink.
18	A. Yes.	18	So you have to un-crosslink, open it
19	Q is that fair?	19	up. And for some antigens, it's it's enzymes
20	A. Yes. At this point it would be,	20	usually, it is a protease, weakened protease.
21	thoroughly.	21	Q. And that's only applied for four
22	Q. Once the paraffin processing takes	22	minutes?
23	place, the specimen is typically cut into a	23	A. It depends, I mean, these are
24	four-micron thick slice with what's called a	24	tested sometimes manufacturer gives
25	A. Microtome.	25	instructions, sometimes we have to adjust it. I
	Page 251		Page 253
1	Q. Thank you. Sometimes for the	1	mean, it's a quality assurance process. We use
2	Q. Thank you. Sometimes for the specimens that you reviewed in litigation, those	2	mean, it's a quality assurance process. We use standard tissue to validate the stain and other
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	Page 254		Page 256
1	little higher. I mean, there is a range of it	1	parts were and degraded were exposed to exactly
2	depends on what retrieval is done and how it is	2	the same environment, heating chemicals.
3	done. But there is a degree of heating involved in	3	BY MS. BYARD:
4	some of the techniques.	4	Q. And I'm not making a distinction
5	Q. Celsius, 37 degrees celsius?	5	between the degraded and the degraded bark as
6	A. 37 degrees celsius, sorry. I	6	you've coined the term, and the non-degraded core.
7	completely forgot you're on a different scale.	7	I'm talking about the virgin samples of
8	Q. So as the specimen is undergoing	8	mesh, off the shelf, that you examined?
9	paraffin embedding for 12 to 24 hours, it may be	9	A. Virgin tissue was exposed to
10	maintained at 37-degree celsius?	10	exactly the same temperatures and chemicals.
11	A. 37 or higher. I mean, depends.	11	Q. I'm talking about virgin mesh.
12	Sometimes there's no retrieval at all, it just	12	A. Virgin mesh. Um, virgin mesh,
13	stain it the way it is; without retrieval. So	13	sorry. Yes.
14	there is no temperature, and no, um, higher	14	Q. It was, okay.
15	temperatures.	15	Did you expose the virgin mesh to all
16	Q. If you were going to say that the	16	the same staining procedures that we've discussed?
17	specimens are subjected to heat up to a certain	17	А. Н&Е.
18	temperature, what would you what would be the	18	Q. Just H&E?
19	"up to" amount?	19	A. Yes.
20	A. 90 degrees centigrade, highest. I	20	Q. When you examine the mesh for the
21	don't think it will go beyond in any of the steps.	21	litigation cases for whether or not the sample
22	Q. And where would you use those	22	absorbs dye, are you just using H&E stain?
23	higher temperatures for processing?	23	A. I think it's incomplete question.
24	A. Paraffin. Usually, the highest	24	To observe what?
25	temperature would be melting point of a paraffin,	25	Q. In paragraph 6 where you talk
	Page 255		Page 257
1		1	Page 257 about the absorption of the mesh of histological
1 2	Page 255 maybe 80 degrees, maybe 90, I'm not sure now. Because I think if it's too high, the paraffin is	1 2	
	maybe 80 degrees, maybe 90, I'm not sure now.		about the absorption of the mesh of histological
2	maybe 80 degrees, maybe 90, I'm not sure now. Because I think if it's too high, the paraffin is	2	about the absorption of the mesh of histological dyes?
2	maybe 80 degrees, maybe 90, I'm not sure now. Because I think if it's too high, the paraffin is brittle, it's melting point is high. If it's	2 3	about the absorption of the mesh of histological dyes? A. No. H&E and trichrome, and even
2 3 4	maybe 80 degrees, maybe 90, I'm not sure now. Because I think if it's too high, the paraffin is brittle, it's melting point is high. If it's lower, it becomes too soft.	2 3 4	about the absorption of the mesh of histological dyes? A. No. H&E and trichrome, and even immunoperoxidase, its counterstain was hematoxylin
2 3 4 5	maybe 80 degrees, maybe 90, I'm not sure now. Because I think if it's too high, the paraffin is brittle, it's melting point is high. If it's lower, it becomes too soft. I would say probably closer to 80 than	2 3 4 5	about the absorption of the mesh of histological dyes? A. No. H&E and trichrome, and even immunoperoxidase, its counterstain was hematoxylin and it stains the degraded layer.
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THE WITNESS: Could you repeat the question? BY MS. BYARD: O. Sure. So looking at specimens, emesh and tissue, you applied multiple different stains? A. For some MR. ORENT: Objection. THE WITNESS: - specimens, I only had the MR. ORENT: Objection. THE WITNESS: - specimens, I only had the mesh for degradation then in your report, you are not assured that the assured. THE WITNESS: That is correct. Because the are no purpose for other stains. BY MS. BYARD: O. Okay. So when you're examining the mesh for degradation then in your report, you are looked at mesh for degradation, you never cleaned the samples to remove the tissue, right? A. No. ORENT: Objection. Asked and degradation, you never cleaned the samples to remove the tissue, right? A. No. ORENT: Objection. Page 259 a foreign body? A. I don't understand the question, or are you reading from Q. I was asking. I was asking you, as a pathologist, are there processes that you would use if you wanted to, tremove tissue from a forcign body? A. No, not really. Because we cut through specimens, so it would be totally separated. Page 259 A. No, not really. Because we cut through specimens, so it would be totally separated. A. No, not really. Because we cut through specimens, so it would be totally separated. A. No, not really. Because we cut through specimens, so it would be totally separated. A. No, not really. Because we cut through specimens, so it would be totally separated. But we don't have to, because we slice are served. A. No, not really. Because we cut through specimens, so it would be totally separated. A. No, not really. Because we cut through specimens, so it would be totally separated. A. No, not really. Because we cut through specimens, so it would be totally separated. But we don't have to, because we slice are served. A. No, not really. Because the cut of the microtome is different ways, right? A. Yes. O. Okay. There's a way to do that if you wanted to, though, right? A. A. No. What do you define as the plane of the mes	1	MR. ORENT: Objection.	1	Actually, you don't want tissue to be
4 DYMS, BYARD: 5 Q. Sure. So looking at specimens, 6 mesh and tissue, you applied multiple different 7 stains? 8 A. For some 9 MR. ORENT: Objection. 10 THE WITNESS: - specimens, I only had 11 H&E. For some specimens I had more than H&E. 12 BYMS, BYARD: 13 Q. Okay. But for the virgin mesh 14 samples you only used H&E? 15 MR. ORENT: Objection. Asked and 16 answered. 17 THE WITNESS: That is correct. Because the are no purpose for other stains. 18 BYMS, BYARD: 19 BYMS, BYARD: 20 Q. When you looked at mesh for degradation, you never cleaned the samples to remove the tissue, right? 21 degradation, you never cleaned the samples to processes that you would use to remove tissue from 1 forcing body? 22 A. I don't understand the question, or are you reading from 23 a foreign body? 24 A. I don't understand the question, or are you reading from 25 grocesses that you would use to remove tissue from 2 forcing body? 3 a foreign body? 4 A. No, not really. Because we cut through specimens, so it would be totally separated. 11 Q. Okay. There's a way to do that if you wanted to remove tissue from 2 forcing body? 3 A. I read an article, some reacreachers use separation to observe the surface, yes, yes. 4 MR. ORENT: Objection. Compound asked and and answered. 11 THE WITNESS: Yes. That summarizes. 12 MR. ORENT: Objection. Asked and and definition. Compound asked and and and and and sister, summarizes. 14 WITNESS: Yes. That summarizes. 15 BYMS, BYARD: 16 BYMS, BYARD: 17 A. More of the gradation then in your report, you define as the while if still in the surrounding tissue, right? 18 off. 19 Q. Okay. And in all the figures cross section like the slice of salami falls off. 19 Q. Okay. And in all the figures remove the tissue, right? 21 specimens are miboded in tissue, right? 22 A. Yes. 23 A. No. 24 Q. As a pathologist, are there processes that you would use to remove tissue from a forcing body? 24 A. You would wish the samples to remove tissue from a forcing body? 25 A. I don't understand the question, or are you reading fr	2		2	
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8 A. For some 9 MR. ORENT: Objection. 111 MTNISS: specimens, I only had 11 H&E. For some specimens I had more than H&E. 12 BY MS. BYARD: 13 Q. Okay. But for the virgin mesh 14 samples you only used H&E? 15 MR. ORENT: Objection. Asked and 16 answered. 17 THE WTNISS: That is correct. Because 18 there are no purpose for other stains. 19 BY MS. BYARD: 19 GNA, ORENT: Objection Asked and 20 Q. When you're examining the mesh for degradation then in your report, you are looking at the mesh while it's still in the surrounding tissue, right? 21 A. Most of the time. Occasional filaments are kind of sticking out, or they are cross section like the slice of salami falls off. 21 degradation, you never cleaned the samples to remove the tissue, right? 22 remove the tissue, right? 23 A. No. 24 Q. As a pathologist, are there 25 processes that you would use to remove tissue from 26 a pathologist, are there processes that you would use if you wanted to remove tissue from a foreign body? 2 A. I don't understand the question, or are you reading from 4 Q. I was asking. I was asking you, as a pathologist, are there processes that you would use if you wanted to remove tissue from a foreign body? 3 A. No, not really. Because we cut through specimens, so it would be totally 3 esperated. 4 Q. Okay. There's a way to do that if you wanted to, though, right? 4 Q. Okay. There's a way to do that if you wanted to, though, right? 5 A. Yes. 6 Q. So, mesh has a length, a fiber, and it has a width of fiber within its knitting structure, right? A. What do you define as the plane of the mesh? 4 Page 261 5 Processes that you wanted to, though, right? 5 A. Was a pathologist, are there or love in the three-dimensional space of the samples are embedded in tissue, right? A. Yes. Q. So when the knife of the microtome is cutting the specimen, you are not assured that the emsh fibers or revent in the proper dicular and angled	7		7	MR. ORENT: Objection. Compound asked
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Page 262 Page 264 1 Q. And the mesh might not be oriented 1 of angle from 90 degrees to almost, um, almost 2 in the specimen, along the length of the specimen, 2 parallel orientation, anywhere. 3 right? 3 I mean, pretty much any specimen if 4 4 it's large enough, you will find a range of angles. A. Let's separate. Filaments, 5 individual filaments and the mesh. 5 Q. So not every slide is a 90-degree 6 6 Q. That's what I was trying to do. cross section of all of the mesh fibers contained 7 You're the one who went to the mesh within the 7 in that section of the specimen? 8 larger specimen potentially being folded. 8 A. That's correct. 9 Let's take out for now, just the 9 MR. ORENT: Objection. 10 fibers, the filaments of mesh itself? 10 BY MS. BYARD: 11 A. That's okay. 11 Q. Does polarized light reflect off 12 Q. So because you don't know how the 12 different thicknesses of material differently? 13 mesh is oriented in the specimen --13 A. I'm not sure exactly what you're 14 14 asking. If it brightens, it will be different if A. Mesh filament or the mesh? 15 O. We'll get to that. 15 the thickness of the material is different? Yes. 16 So because you don't know how the mesh, 16 If it's getting thicker, there will be 17 17 more material, it will -- to a certain degree, I as a whole, is oriented in the specimen, you 18 similarly don't know how the individual fibers are 18 mean, that's to a certain degree I mean, so... 19 Q. It will get brighter or dimmer? oriented in the specimen --19 20 A. No, this is not correct. 20 A. If it's clear, it will get -- to a certain degree, it will get brighter. When it's 21 Q. -- right? 21 really thin, the brightness will be lower and then 22 A. I can go -- mesh filament is 22 23 around the structure. So if it's cut 23 it will build up. And then after a certain thickness, it will not matter anymore. So it 24 perpendicular, there is a round cross section. If 24 25 it is oblique, then you get an oval, and then 25 reaches full capacity. Page 263 Page 265 1 sometimes you get a really long sort of cross 1 Q. Okay. So if I was looking at a 2 section. 2 thinner amount of material that was clear, under 3 So just by the shape, I can tell you 3 polarized light, it would be brighter or dimmer 4 exact, approximately what's angle. 4 than thicker amounts of that same material? 5 5 Q. Do you measure each one of the A. If it's clear, because polarizable 6 mesh shapes that you look at to assure that they 6 materials may be clear or not clear, so then 7 7 are perfectly round? there is a --8 8 A. There is a bunch of different Q. It's clear in this hypothesis. 9 shapes, and some of them are round, some of them 9 A. If it's clear, and it's really --10 are oval. So the more longer oval you get, the 10 if it gets thicker -- I mean, start from very thin, 11 more angle -- I mean, more acute angle is. 11 barely visible. So the brightness of the light 12 12 Q. And so the way that you've will be dimmer. 13 represented mesh in your colorized figures is with 13 And then with increasing thickness, the 14 yellow, right? 14 brightness will be going up, up until it reaches 15 A. Yes. 15 full capacity. I mean, beyond which it cannot get 16 Q. And many of those shapes, you'll 16 any brighter. And then there might be some 17 concede, are not perfect circles, they're ovals; 17 influence with light transmission and so forth 18 aren't they? 18 there so ... 19 A. Yes. They are angled. 19 Q. Okay. I think I understand, thank 20 Q. And so when the knife of the 20 you. 21 21 microtome is cutting each specimen to create a A. But these sections I cut all at four microns. All tissue within the one section is 22 slide, each mesh fiber or filament is not being cut 22 23 at a 90-degree angle in every circumstance, 23 exactly the same thickness. 24 24 Q. Not if it's not cut at a 90-degree 25 angle, right? 25 A. That's correct. There is a degree

	Page 266		Page 268
1	A. No, it's all four microns.	1	And in none of these figures do we see
2	Q. If the material is oriented at an	2	the entire circumference of the mesh filament, do
3	angle, and not completely 90 degrees	3	we?
4	A. It's still four microns.	4	A. No, because it doesn't fit. Well,
5	Q to the knife	5	the thickness of this degraded layer is anywhere
6	A. It's four microns. Can I draw it?	6	between two to six microns. Filament is up to
7	Q. It's a three-dimensional space,	7	here. It wouldn't fit.
8	though.	8	Q. Okay. So in the at the level
9	A. No, it's a slice. So if you get	9	of magnification that you need to view this narrow
10	slice like this, four microns. If you get slice	10	margin, what you call the degraded bark, you're not
11	like this, four microns. If you get slice like	11	able to capture the entire circumference of the
12	this, it's oblique, it's still four microns.	12	mesh filament in your imaging?
13	Q. But the way the material is angled	13	A. Yes. This magnification size of
14	within the specimen is tilted?	14	filament is much larger, several pages larger. In
15	A. Yes. But it's still four microns	15	some lower magnification, you can still see the
16	thickness. The cross section is four microns	16	degraded layer, but it's much less details.
17	thick, it doesn't matter what orientation, it's	17	Q. One question I had was how you're
18	still four microns. Doesn't matter how you're in	18	able to tell that there isn't tissue interposed
19	it, four microns. It's like a salami.	19	over the edge of the filament, and your eye,
20	Q. But if you look at it from looking	20	through the microscope.
21	up, you would be looking through less material on	21	So if you're able to answer that, if
22	the far edge of the material if it was oriented	22	not I can rephrase.
23	sideways?	23	A. How do I see if there's no tissue
24	A. Or the very edge, the very tip of	24	overlapping with the filament? Sometimes it is,
25	this, yes. It will be somewhat different, yes.	25	just play with focus. Because it goes like this.
	,,,		just play with rooms. Because it goes like tims.
	Page 267		Page 269
1	Page 267 Q. Okay, thank you. Thank you.	1	Page 269 It's a different plane of focus, so you cannot
1 2		1 2	
	Q. Okay, thank you. Thank you. THE VIDEOGRAPHER: Excuse me, Counsel. I have to change the tape.	l .	It's a different plane of focus, so you cannot
2	Q. Okay, thank you. Thank you. THE VIDEOGRAPHER: Excuse me, Counsel.	2	It's a different plane of focus, so you cannot focus on exactly the same. Even within four
2	Q. Okay, thank you. Thank you. THE VIDEOGRAPHER: Excuse me, Counsel. I have to change the tape.	2 3	It's a different plane of focus, so you cannot focus on exactly the same. Even within four microns, you can focus only within very narrow range. So, essentially, you're looking at the
2 3 4	Q. Okay, thank you. Thank you. THE VIDEOGRAPHER: Excuse me, Counsel. I have to change the tape. MS. BYARD: Perfect, let's take a	2 3 4	It's a different plane of focus, so you cannot focus on exactly the same. Even within four microns, you can focus only within very narrow range.
2 3 4 5	Q. Okay, thank you. Thank you. THE VIDEOGRAPHER: Excuse me, Counsel. I have to change the tape. MS. BYARD: Perfect, let's take a break.	2 3 4 5	It's a different plane of focus, so you cannot focus on exactly the same. Even within four microns, you can focus only within very narrow range. So, essentially, you're looking at the
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2 3 4 5 6 7 8	Q. Okay, thank you. Thank you. THE VIDEOGRAPHER: Excuse me, Counsel. I have to change the tape. MS. BYARD: Perfect, let's take a break. THE VIDEOGRAPHER: This marks the end of media number three in the deposition of Dr. Vladimir Iakovlev. We are going off the record at 5:28 p.m.	2 3 4 5 6 7 8 9	It's a different plane of focus, so you cannot focus on exactly the same. Even within four microns, you can focus only within very narrow range. So, essentially, you're looking at the slice which is much thinner than four microns. Probably you'll be in the focus of a range of one micron thickness only. The rest will be blurred. Like this picture, you mentioned 32. You see this is completely blurred. And it's
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	Page 270		Page 272
1	Q. You would agree, though, that it	1	THE WITNESS: I'm telling you.
2	is typical for there to be some tissue overlapping	2	BY MS. BYARD:
3	the circumference of the mesh filament on cross	3	Q. You're telling me, but I don't
4	section?	4	have the underlying data, right?
5	A. No. Typical is contraction, so	5	MR. ORENT: Objection.
6	tissue contracts during dehydration, it splits and	6	THE WITNESS: That's correct.
7	goes away. Usually, the way when it overlaps, when	7	BY MS. BYARD:
8	it lifts up, floats and sits on tissue.	8	Q. Okay. Looking at paragraph 7 of
9	But if it sits in situ, this should	9	your report, sir, on page 6. You write that:
10	contract and retracts. So usually there is a	10	"The published literature
11	separation. Sometimes there is not on edges, but	11	indicates that the main
12	overlap with the tissue is least common phenomena.	12	complications of transvaginal mesh
13	Again, any overlap in the field will	13	devices leading to mesh excision are
14	not be visible because of the depth of sharpness.	14	chronic pelvic pain, pain with
15	I can focus on the very narrow depth. You can have	15	intercourse, parenthesis, [dyspareunia],
16	15-microns difference with different layers, and if	16	de novo, worsening urinary symptoms
17	you have enough light which is passing through, you	17	and mucosal erosion, parenthesis,
18	can gradually see layer by layer, and steady	18	[mesh exposure]."
19	details within these 15 microns.	19	Which articles are you relying on for
20	Q. Have you continued soaking that	20	that statement?
21	virgin mesh or other virgin mesh samples in	21	A. Clinical.
22	formalin?	22	Q. Are there articles in your list of
23	A. Yeah, I have some still sitting in	23	materials reviewed that you can point me to for
24	formalin.	24	that proposition?
25	Q. When was the last time that you	25	A. The regular complications? Yes.
	Page 271		Page 273
1		1	
1 2	Page 271 examined them for degradation? A. Sometime during summer. But	1 2	I mean, there are some clinical articles there.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	A. Sometime during summer. But sometimes I completely use up the sample, so I have to start the process again, so it's not the first mesh was exposed, I think last fall. But I don't think I have samples from that time, so there will be I just have dates written on the jars, so Q. Okay. And the longest still it's been in formalin is four months? A. Four months. It's way beyond the when I was writing this manuscript, we talk about, about 25 percent of the samples had exposure time less than a month. And about 8 or 10 percent of the specimens I examined had exposure to formalin less than 72 hours. And they still showed the same degradation layer, so Q. And you're referring to one of your published studies? A. In preparation. But I'm just telling you the date. So four months is overkill by many fold. Q. Okay. And that's not data that we have yet, right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	I mean, there are some clinical articles there. Q. Any in particular that you would cite for support for that proposition? A. I would have to check these papers again, sorry. Because it's been quite sometime. I don't remember exactly which article specifies, but Q. Now in contrast, your data that you publish with Dr. Carey indicated that the number one reason for excision in the samples that you reviewed there, were for exposure, correct? A. You mean mucosal exposure? Yes. Q. Okay. If I were to ask you what the rate in the medical and scientific literature of excision for dyspareunia was, compared to the rate of excision for dyspareunia in your 120 specimens, you couldn't cite me those numbers, could you? A. I would have to go through papers and the rate will be different in each paper, and there is no such thing as the same rates. So there will be a range of rates. Q. And that analysis hasn't been completed, has it?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Sometime during summer. But sometimes I completely use up the sample, so I have to start the process again, so it's not the first mesh was exposed, I think last fall. But I don't think I have samples from that time, so there will be I just have dates written on the jars, so Q. Okay. And the longest still it's been in formalin is four months? A. Four months. It's way beyond the when I was writing this manuscript, we talk about, about 25 percent of the samples had exposure time less than a month. And about 8 or 10 percent of the specimens I examined had exposure to formalin less than 72 hours. And they still showed the same degradation layer, so Q. And you're referring to one of your published studies? A. In preparation. But I'm just telling you the date. So four months is overkill by many fold. Q. Okay. And that's not data that we	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	I mean, there are some clinical articles there. Q. Any in particular that you would cite for support for that proposition? A. I would have to check these papers again, sorry. Because it's been quite sometime. I don't remember exactly which article specifies, but Q. Now in contrast, your data that you publish with Dr. Carey indicated that the number one reason for excision in the samples that you reviewed there, were for exposure, correct? A. You mean mucosal exposure? Yes. Q. Okay. If I were to ask you what the rate in the medical and scientific literature of excision for dyspareunia was, compared to the rate of excision for dyspareunia in your 120 specimens, you couldn't cite me those numbers, could you? A. I would have to go through papers and the rate will be different in each paper, and there is no such thing as the same rates. So there will be a range of rates. Q. And that analysis hasn't been

	Page 274		Page 276
1	THE WITNESS: What do you mean, which	1	A. No, but
2	analysis?	2	Q. Okay, thank you.
3	BY MS. BYARD:	3	You write here in paragraph 7, that
4	Q. Comparing the range of reported	4	this is consistent with random sampling since the
5	rates of dyspareunia as the reason for excision in	5	samples had variable sources and manufacturers; do
6	the published literature, with the rate of excision	6	you see that?
7	for dyspareunia in your sample size of 120	7	A. Yes, they were coming from
8	specimens?	8	different sources, from they were of different
9	A. If I published this comparison?	9	manufacturers. They were excised for different
10	No, I have not published this comparison.	10	reasons. The range of patient demographics was
11	Q. And you haven't done that	11	large.
12	comparison yet, either, right?	12	Q. You haven't set up a registry,
13	A. Well, roughly I estimated.	13	though, for mesh excisions in the transvaginal mesh
14	Because you can see in the papers what is	14	example like you have for hernia mesh in your study
15	percentage of those excised for where is it?	15	with Dr. Bendavid, right?
16	Q. It was Exhibit 1198.	16	A. No. Those samples are obtained
17	A. So if we split now, see I have	17	prospectively, these samples were obtained
18	I had 67 percent exposure, 56 percent pain, and	18	retrospectively.
19	overlap between them, 33 percent.	19	Q. And the sources were threefold.
20	Q. That was for 24 specimens, though?	20	They were either St. Michael's, they were other
21	A. Yeah, that was a pool size in	21	hospitals, and they were from the Plaintiffs'
22	that. If you're asking for complete set, no. And	22	lawyers through various
23	this set is growing every day, I mean I'm receiving	23	A. But when they come from lawyers,
24	samples, so	24	they're not coming from one specific individual.
25	Q. So for the set of 120 specimens,	25	They're coming from different excising surgeons,
1	you can't tell me what the rate of complications	1	different states, different hospitals of you
2	were prompting the revision surgery, right?	2	make it sound as if lawyers, just one person, one
3	MR. ORENT: Objection.	3	clinician and one lab, no. It's all over, you know
4	THE WITNESS: I can estimate the range	4	that.
5	anywhere from 30 to 50 percent, somewhere. It	5	Q. And your research on hernia repair
6	depends on the I mean, again	6	mesh, you didn't receive samples from Plaintiffs'
7	BY MS. BYARD:	7	lawyers, right?
8	Q. You don't have those numbers or	8	MR. ORENT: Objection.
9	those statistics analyzed yet, correct?	9	THE WITNESS: Which research?
10	A. Not for the total number of	10	BY MS. BYARD:
11	specimens I received by today. I mean, I	11	Q. The study that you published with
12	initially, as for this study, I did analysis; and	12	Dr. Bendavid?
13	then I think I did analysis sometime in between.	13	A. The SIN paper? No, there was no
14	But I mean, I have not done it like yesterday	14	litigation cases in this paper.
15	Q. Okay.	15	Q. Paragraph 8 continues:
16	A for all specimens I receive.	16	"Pain is reported as the most
17	Q. The numbers you can quote for me	17	frequent complication of a mesh
18	today are from these 24 samples that are that	18	procedure in published literature
19	have been analyzed in the study that you published	19	and in the clinical records that I
20	with Dr. Carey that's Exhibit 1198?	20	reviewed."
	A. This is just the paper in front of	21	Do you see that?
21			
21 22	me. I might have the number on the spreadsheet in	22	A. That's correct.
21 22 23	me. I might have the number on the spreadsheet in my log of specimens.	23	Q. Which study are you relying on for
21 22	me. I might have the number on the spreadsheet in		

Page 278 Page 280 1 where the pain was higher. Sometimes there are 1 entrapped in tissue that was never exposed to mesh, 2 other -- pain is a very subjective subject, and 2 3 sometimes it's not assessed. There is no primary 3 A. No, this is not correct. If you 4 4 goal of the studies to assess pain, so they just take tissue as a general, there cannot be 5 provide statistics. When the study is more focused 5 entrapment because there is no tight area. 6 6 on pain, the numbers might be higher. So it's a Entrapment happens in specific anatomical locations 7 7 range. where there is a tunnel, or there is a compartment. 8 Q. And the studies that you reviewed, 8 I'm talking about normal, spontaneously occurring 9 what was the range of reported pain as a reason for 9 sort of entrapment or tunnel syndromes. 10 excision? 10 This is not happening in, in tissue as 11 A. You mean percentage-wise? I don't 11 we talk about it. It's like a tunnel, usually 12 remember now, but I mean there were a number of 12 surrounded by some kind of winding, synovial 13 studies which showed pain as a first -- the number 13 winding of the place, tight spot where nerves pass 14 was higher, higher than anything else. 14 through. 15 Q. Are you referring to hernia mesh 15 Q. So if I understand your testimony 16 literature or transvaginal mesh literature? 16 correctly, you can have nerve entrapment in the 17 A. Transvaginal mesh. And this is 17 body, even if there's not any mesh, against certain 18 just complication, it's not a reason for excision. 18 anatomical structures, or tunnels, or compartments 19 You see, if you read this, "the pain is 19 as you've described it? 20 the most frequent complication." So if you go 20 MR. ORENT: Objection. 21 through it, it may go up to 30 percent, even higher 21 THE WITNESS: I mean, usually there is 22 in some literature. Some literature it goes -- in 22 some degree of pathology called changes in the 23 some publications it goes lower. 23 area. It's not normal to have an entrapment 24 Q. As you were reviewing the medical 24 syndrome. 25 literature on complications of transvaginal mesh, 25 Page 279 Page 281 1 did you keep any notes on what the reported rate of 1 BY MS. BYARD: 2 2 complication was for different symptoms? Q. Sure. But what I want to focus on 3 A. No. Because I wasn't writing a 3 here are abnormal pathological findings that are 4 paper for that specific, it was just a memory of my 4 mechanisms for pain. 5 understanding. And I want to focus on abnormal 6 6 Q. Do you agree that innervated pathological findings that are mechanisms for pain, 7 7 tissue, anywhere in the body, can be subject to and whether those mechanisms exist without mesh? 8 potential pain mechanisms of direct irritation to 8 A. In the vaginal area, no. There 9 the nerves? 9 are no anatomical locations, or specific anatomical 10 A. Yes. 10 structures to cause nerve entrapment without mesh. Q. Entrapment? 11 11 Q. Without mesh you can never have 12 A. Entrapment in normal tissue? 12 nerve entrapment in the vagina; is that your 13 13 Q. (Nods.) testimony? 14 A. If entrapment happens, it's 14 MR. ORENT: Objection. 15 THE WITNESS: If there is no mesh and 15 abnormal. I mean, if you assume that there are 16 places in the body which can cause entrapment 16 there is no other pathological condition, like a 17 syndromes, the entrapment itself becomes abnormal. 17 tumor or something else, it cannot happen. 18 Q. Sure. And I'm talking about 18 BY MS. BYARD: innervated tissue anywhere in the body can present 19 19 Q. Okay. So if there is a tumor you 20 a finding of entrapment on histological examination? 20 can have nerve entrapment? 21 21 A. No, it cannot. Entrapment, in A. That's correct. With tumor, there 22 normal circumstances, occurs in tight spaces where 22 will be little bit different mechanisms. But there 23 nerves pass by. So these are very specific 23 will be effected nerves. 24 anatomical locations. 24 Q. Okay. If there's another foreign 25 25 Q. It's possible for nerves to be body besides the mesh in the vagina, there could be

	Page 282		Page 284
1	nerve entrapment?	1	BY MS. BYARD:
2	A. If there is foreign body with	2	Q. That's a very fair point. The
3	compartment.	3	entire reason you have identified these potential
4	Q. Okay. Innervated tissue anywhere	4	pain mechanisms with mesh, is because these are
5	in the body can be exposed to pain mechanisms that	5	well understood mechanisms for pain in the
6	are inflammatory in nature, right?	6	literature, apart from any findings related to
7	A. Spontaneously occurring	7	mesh, correct?
8	inflammatory conditions, that's what you mean?	8	A. Yes. But, when I examine
9	Q. Any sort of inflammatory mechanism	9	specimens, I don't find anything else except for
10	of pain.	10	changes related to the mesh. I don't find the
11	MR. ORENT: Objection. Vague.	11	tumor, I don't find musculitis, which can cause
12	THE WITNESS: As we stated before, as I	12	necrosis of the vessels.
13	stated before, inflammation alters sensitivity	13	So, part of my job as a pathologist, is
14	threshold.	14	to rule out other conditions. And then I see only
15	So any inflammation can build up, so	15	changes which are related to the mesh.
16	the basis for pain, or cause pain if it's	16	Q. As a part of your practice,
17	sufficiently high enough.	17	though, in the litigation context, if you receive a
18	BY MS. BYARD:	18	specimen that's a uterus, and clearly not mesh, you
19	Q. Can compression by edema act as a	19	don't examine it?
20	mechanism for pain for tissue with nerve ingrowth,	20	A. I do examine it.
21	even when there is no mesh present?	21	Q. You do?
22	A. If it's enclosed compartment	22	A. I do, yeah. If I receive a
23	well, see, edema, if there's no walls of a	23	specimen, I look through the microscope.
24	compartment, edema will expand further. If it	24	Q. And do those findings make their
25	grows rapidly, it may cause some discomfort or	25	way into a report that's disclosed to us?
	Page 283		Page 285
1	pain. If there is no compartment, edema will	1	MR. ORENT: Objection.
2	and if it goes slowly, it will just be painless	2	THE WITNESS: I don't remember now.
3	edema. But the problems are when the edema goes	3	BY MS. BYARD:
4	faster; or, if it occurs in enclosed space.	4	Q. Withdrawn.
5	So you need to set some pathological	5	In the absence of mesh, there can also
6	condition. To form this walls of compartment, or	6	be mechanical irritation of receptors, right?
7	place foreign body, and then, to cause edema. And	7	A. Mechanical, if it's normal degree
8	then edema would occur in an enclosed compartment.	8	of stimulation, it will not cause pain. If it's
9	 Q. So in certain pathological 	9	abnormal degree, if it's high enough, it will cause
10	conditions, in the absence of mesh, compression by	10	pain. That's how
11	edema can cause pain?	11	Q. Yes. Exactly.
12	MR. ORENT: Objection.	12	A take a hammer and then it will,
13	THE WITNESS: That's correct.	13	it will hurt without mesh.
14	BY MS. BYARD:	14	Q. Okay.
		1 4-	A Dut if you just mass it with your
15	Q. Even in the absence of mesh?	15	A. But if you just press it with your
15 16	Q. Even in the absence of mesh?A. Yes. That's why I know that edema	16	finger, just feel the touch.
16	A. Yes. That's why I know that edema	16	finger, just feel the touch.
16 17	A. Yes. That's why I know that edema can cause pain, because there are conditions which	16 17	finger, just feel the touch. Q. Ending paragraph 8 you write:
16 17 18	A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling.	16 17 18	finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with
16 17 18 19	A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling. Q. Thank you.	16 17 18 19	finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with clinical findings of pain, particularly
16 17 18 19 20	A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling. Q. Thank you. Is the same true for ischemia?	16 17 18 19 20	finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with clinical findings of pain, particularly chronic pain in women."
16 17 18 19 20 21	A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling. Q. Thank you. Is the same true for ischemia? MR. ORENT: Objection.	16 17 18 19 20 21	finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with clinical findings of pain, particularly chronic pain in women." Do you see that? A. Yes.
16 17 18 19 20 21 22	A. Yes. That's why I know that edema can cause pain, because there are conditions which cause pain through the swelling. Q. Thank you. Is the same true for ischemia? MR. ORENT: Objection. THE WITNESS: For ischemia, yes.	16 17 18 19 20 21 22	finger, just feel the touch. Q. Ending paragraph 8 you write: "These findings correlate with clinical findings of pain, particularly chronic pain in women." Do you see that?

Page 286 Page 288 1 A. Clinical pathological correlation. 1 excise, you cause damage, and there is more 2 So when I receive a specimen, and described as 2 scarring. Because when you do multiple procedures 3 removed for reasons of pain, as I said, I examine 3 throughout, the scar is there. So there might be 4 4 some residual changes in there. So the initial it for pathological findings, I rule out natural 5 5 occurring non-mesh-related conditions, then examine cause of these changes would be still mesh. 6 6 what happened in the mesh. So, that's what it How do you separate all of this? And 7 7 meant. how do you ascertain completeness of excision? How 8 Q. Okay. And so it's not as if 8 they are certain that the postexcision changes are 9 you're looking at a pathological -- a pathology 9 not residual changes which occurred while mesh was 10 10 slide and saying, "aha, it was this edema that there? This is difficult. caused all this pain that she reported." Right? 11 11 BY MS. BYARD: MR. ORENT: Objection. 12 12 Q. You would agree that correlation 13 13 THE WITNESS: See, when I receive a isn't causation, though, wouldn't you? 14 14 MR. ORENT: Objection. specimen, I know that there was pain, and it's 15 15 indicated that -- sometimes I look at the history THE WITNESS: See, when you use 16 16 later. So I know that there was pain, and I do causation, do you use it in -- let me ask, I mean, 17 17 clinical pathology called correlation. just to clarify this. 18 18 You cannot -- it's not a game, I mean, When you use word "causation," do you 19 mean "prediction"? Or correlation of clinical 19 it's a diagnostic process. You have to take all 20 picture with the pathological findings? information available to you and then correlate. 20 21 21 Clinical investigation was done because BY MS. BYARD: 22 22 of pain, they narrowed down problem to the excised Q. I guess maybe the better way to 23 23 ask it is that the word you used here was mesh, I received a specimen. So I already know 24 24 "correlate," right? Not "cause"? that there was a problem, complication, that's why 25 A. And I explain it. Correlation is 2.5 it was excised. Page 287 Page 289 1 Then I try to figure out what was 1 clinical pathology calculation. Patient comes with 2 causing it, what is abnormal in the specimen which 2 complication, symptoms. So that's where clinical 3 was removed as a part of treatment of the 3 part comes in. And there's investigation, there's 4 complications, or patient's symptoms. And then I 4 narrowing down, and then I examine the specimen to 5 5 rule out naturally occurring, I don't see it, and see what is abnormal in it. So this is diagnostic 6 6 then I see this. process and treatment process. 7 7 And then, if somebody tells me, "I have If you're talking about prediction, 8 8 what can happen in the future is something a pain." And I examine the specimen, and there is 9 mesh with edema, with nerve ingrowth, this is the 9 occurring now, that's not how medicine works. 10 cause of pain. Because there is nothing else in 10 So the correlation here, correlation the specimen which would explain it. 11 between what was clinically seen abnormal, and what 11 12 12 BY MS. BYARD: I see in the microscope. 13 13 Q. So you're relying, in large part Q. Now, if that patient's pain 14 14 continues after that mesh is excised, you can then then, on the clinical determination that's made by 15 15 agree with me that the edema, or the foreign body the treating physician, that the doctor and the 16 inflammation can no longer be considered the cause 16 patient should at least try to excise the mesh to 17 of those symptoms, right? 17 address the patient's symptoms, right? MR. ORENT: Objection. 18 18 A. Yes. 19 THE WITNESS: If entire mesh is excised 19 Q. You also write that: 20 20 "Placement of vaginal tissue --" without damage to the tissue, which is 21 hypothetical, I don't think most of the meshes can 21 and I'm looking at paragraph 9 now, 22 be excised completely, or completeness of excision 22 Doctor. "-- is associated with a 23 can be as certain. So the first difficult part of 23 higher risk of chronic pain issues 24 24 than the placement of abdominal mesh -the statement. 25 25 abdominal hernia mesh." Excuse me.

73 (Pages 286 to 289)

The second difficulty is that when you

	Page 290		Page 292
1	A. That's correct.	1	it's personal experience of each individual.
2	Q. And what literature are you citing	2	But the studies who studied further,
3	for that proposition?	3	how it happens with inflammatory mediators and
4	A. Again, clinical literature. Being	4	other things, yeah, they are there.
5	in the hernia is lower, somewhere in the range from	5	Q. There are studies that exist?
6	about 10 percent or so, but for transvaginal meshes	6	A. There should be at least in that.
7	it can go up to 30 percent.	7	Q. Okay. Are there studies looking
8	Again, it's very, very difficult to	8	more specifically at inflammation and foreign body
9	compare the studies, because they use different	9	reaction in the presence of mesh, and whether that
10	questionnaires and different approaches.	10	heightens the sensitivity threshold of pain
11	Q. And are you talking about rates of	11	receptors?
12	chronic pain as a complication overall, or is it	12	A. It's almost like narrowing down
13	complication leading to excision in this statement?	13	something to a specific area, like could there be a
14	A. Complication overall.	14	doctor for a little right finger.
15	Q. We talked earlier about how the	15	Q. The answer is, "no," right?
16	vagina compared to the abdominal wall, as a	16	A. There are studies which study
17	nerve-rich environment, right?	17	inflammation, in general. I mean, there's a
18	A. Yes.	18	physician or any thinking person, you can apply it
19	Q. And you would also agree with me	19	to any areas so
20	then, that the vagina as an area of the body is	20	Q. So the answer to my question is,
21	associated with a higher risk of chronic pain	21	no, the literature doesn't get that specific,
22	compared to the abdomen, because it is a more	22	right?
23	nerve-rich environment, right?	23	MR. ORENT: Objection.
24	A. Yes.	24	THE WITNESS: Not that narrow.
25	Q. And that's true in the absence of	25	THE WITHESS. Not that harrow.
	(
	Page 291		Page 293
1	Page 291 mesh, too, isn't it?	1	Page 293 BY MS. BYARD:
1 2		1 2	
	mesh, too, isn't it? A. Yes. Q. You conclude paragraph 10, with		BY MS. BYARD:
2	mesh, too, isn't it? A. Yes.	2	BY MS. BYARD: Q. Thank you. Let's look at page 8,
2	mesh, too, isn't it? A. Yes. Q. You conclude paragraph 10, with	2 3	BY MS. BYARD: Q. Thank you. Let's look at page 8, please.
2 3 4	mesh, too, isn't it? A. Yes. Q. You conclude paragraph 10, with the statement that:	2 3 4	BY MS. BYARD: Q. Thank you. Let's look at page 8, please. I assume your response will be the
2 3 4 5	mesh, too, isn't it? A. Yes. Q. You conclude paragraph 10, with the statement that: "It is well established that	2 3 4 5	BY MS. BYARD: Q. Thank you. Let's look at page 8, please. I assume your response will be the same, but with respect to transvaginal mesh, or
2 3 4 5 6	mesh, too, isn't it? A. Yes. Q. You conclude paragraph 10, with the statement that: "It is well established that inflamed tissue alters the	2 3 4 5 6	BY MS. BYARD: Q. Thank you. Let's look at page 8, please. I assume your response will be the same, but with respect to transvaginal mesh, or really just polypropylene mesh in general, you
2 3 4 5 6 7	mesh, too, isn't it? A. Yes. Q. You conclude paragraph 10, with the statement that: "It is well established that inflamed tissue alters the sensitivity threshold of pain	2 3 4 5 6 7	BY MS. BYARD: Q. Thank you. Let's look at page 8, please. I assume your response will be the same, but with respect to transvaginal mesh, or really just polypropylene mesh in general, you can't point me to a specific study showing that the
2 3 4 5 6 7 8	mesh, too, isn't it? A. Yes. Q. You conclude paragraph 10, with the statement that: "It is well established that inflamed tissue alters the sensitivity threshold of pain receptors."	2 3 4 5 6 7 8	BY MS. BYARD: Q. Thank you. Let's look at page 8, please. I assume your response will be the same, but with respect to transvaginal mesh, or really just polypropylene mesh in general, you can't point me to a specific study showing that the pain caused by swelling is present in amplified
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Page 294 Page 296 1 Q. Okay. And the same thing is true 1 A. Possibly in some locations, yes. But when I see it in the meshes, everything outside 2 for scar tissue, right? We know that all mesh will 2 3 be present with scar tissue, and yet not all women 3 of mesh is collapsed, and then vessels in the folds 4 4 with mesh experience pain? of the mesh are dilated. 5 5 So, therefore, I have internal control. MR. ORENT: Objection. 6 6 THE WITNESS: See, this is difficult. I see what is outside of the mesh and I see what is 7 7 Because I don't actually have the specimens from inside of the mesh, it's different. 8 women who for sure didn't experience pain, or 8 Q. You've looked at about 120 9 didn't experience any complications. This would be 9 specimens of transvaginal mesh at the time that you 10 10 an autopsy series, which is difficult. authored your report. 11 11 So all cases I receive, they have Do you have any statistics that you can 12 12 complications, all have scars. If those who never cite for me for the rate of dilated and congested 13 13 have any complications, how much of scarring -vessels in non-scarred vaginal tissue that you have 14 there would be scar, if there is a different extent 14 examined in your course as a pathologist. 15 of scarring, I don't know. 15 A. See, normally, you don't see 16 BY MS. BYARD: 16 congestion. Congestion of the vessels is not 17 17 Q. In fact, let me rephrase that. normal. I mean, there has to be something which is Strike that. 18 18 causing it. So if it's normal tissue -- if I quote 19 The fact that women can have scarring 19 it "normal," it means that there are no 20 because of mesh, but not experience pain, tends to 20 pathological findings. 21 call into question, the association between the 21 If I see congestion, and some other 22 presence of that scar tissue around the mesh and 22 changes, I mean, this would not be perfectly 23 pain, doesn't it? 23 abnormal. I mean, there might be some bleeding due 24 24 A. It contributes. The scar itself, to surgery or something else. 25 25 wouldn't be a problem. But scar with mesh, with Q. You can't quote a rate then Page 295 Page 297 1 1 because you don't see it typically; is that what innervation, with connection to other areas, then 2 2 the whole complex of changes, this leads to pain. you're saying? 3 Q. Well, from your research you've 3 A. What do you mean, rate of what happens with --4 concluded that all mesh will have innervation, 4 5 5 right? Q. How often those findings are 6 6 present in non-mesh vaginal specimens? A. Transvaginal? 7 7 Q. (Nods). A. I don't see it. 8 8 A. Yes. Because all meshes I MR. ORENT: Objection. 9 received. But again, I don't know what is 9 THE WITNESS: I don't see it normally. 10 happening in those meshes which don't have any 10 BY MS. BYARD: complications, or patients don't complain to a Q. And I'm using the word "normally" 11 11 12 to describe "commonly". I'm asking about abnormal 12 degree that the mesh is excised. 13 Q. Okay, thank you. 13 pathological findings. 14 14 Have you heard of a condition called A. I don't understand exactly. If 15 pelvic floor congestion syndrome? 15 you want me to tell if I see the difference what is 16 A. Not specifically. 16 inside the mesh of tissue, and what is outside on 17 Q. Do you know if there are ways to 17 the mesh, either in the specimen of mesh or measure blood flow in the pelvis? 18 specimens without the mesh; there is a marked 18 19 A. Dopplar. 19 difference between what is inside the mesh and 20 Q. And you haven't looked at studies 20 outside the mesh. 21 21 on that issue, have you? Q. And I'm thinking about patients 22 A. On Dopplar studies, no. 22 who undergo excisions who have never had mesh. Not 23 Q. Would you agree with me that blood 23 variation within a specimen. 24 vessels can become dilated and congested in the 24 MR. ORENT: Objection. 25 25 THE WITNESS: I don't see any vagina and surrounding area in the absence of mesh?

	Page 298		Page 300
1	congestion. If it's a healthy, elective procedure	1	mesh, muscle contraction results in
2	for hysterectomy, when they do some trimming of the	2	pulling of the entire mesh."
3	vagina, and then they get vaginal cuff, there is no	3	Do you see that?
4	congestion.	4	A. Yes.
5	BY MS. BYARD:	5	Q. Can you point me to any published
6	Q. Okay.	6	articles that show muscle contraction pulling on
7	A. No edema, no congestion, no	7	the mesh?
8	inflammation, is pristine tissue.	8	A. No, it has not been specifically
9	Q. And that's for a patient who's	9	studied in that specific sequence as you word it.
10	undergoing surgery electively, not because the	10	Q. You could design an experiment
11	uterus or surrounding organs, the ovaries, were	11	where you could look at muscle contraction in its
12	identified as being a potential cause of that	12	relationship to mesh, couldn't you?
13	woman's complaints, right?	13	A. What I do see, when I can tell you
14	A. There are complaints. I mean,	14	that if the muscle strength is viable, so it's
15	there is a reason for hysterectomy. Usually it's	15	contractile. Because see, with a muscle, if it
16	dysmenorrhea or just	16	doesn't if it degenerates, it's not contract
17	Q. Heaviness?	17	anymore.
18	A. Excessive bleeding in perimenopausal	18	If it's healthy muscle, it will
19	periods, so they don't want to have to take	19	contract. So those muscle fibers or bundles, I see
20	drugs, so	20	in the mesh, they're healthy. Therefore, they
21	Q. Okay. You write in paragraph 13	21	contract.
22	about muscle relationships with mesh; are you with	22	Q. As far as how the mesh is then
23	me?	23	pulled by that muscle contraction, you could design
24	A. Yes.	24	an experiment, though, looking at, for instance,
25	Q. Can striated muscle grow within	25	3D ultrasound technology?
			Page 301
1		1	Page 301
1 2	the mesh structure?	1 2	A. Oh, if the mesh is moving during
2	the mesh structure? A. That's a difficult question.	2	A. Oh, if the mesh is moving during movements, and yeah, you can do it. I mean, you
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	Page 302		Page 304
1	This is my interpretation of the microscopic	1	MR. ORENT: Objection.
2	findings, that's what I'm trained to do. Interpret	2	BY MS. BYARD:
3	what I see in the microscope, so	3	Q right?
4	BY MS. BYARD:	4	A. That's correct.
5	Q. You haven't tested that finding in	5	Q. There are ways to measure the
6	living patients, right?	6	forces at work in the body, aren't there?
7	MR. ORENT: I'm not sure if he was done	7	A. You have to explain a little bit
8	with his prior answer.	8	more, what do you mean "forces in ways"?
9	BY MS. BYARD:	9	Q. Well, there are ways that you
10	Q. Oh, sorry.	10	could measure, for instance, the intraabdominal
11	A. See, this is not my job, I mean, I	11	force placed on muscle through, through ultrasound
12	know what tissue does. So if a muscle is healthy,	12	technology, can't you?
13	it contracts. This is what we know based on	13	MR. ORENT: Objection. Vague.
14	mesh, no mesh, we've known it for thousands of	14	THE WITNESS: I'm not sure if you can
15	years, muscle contracts. If it's healthy muscle,	15	use ultrasound to measure the force.
16	it contracts. If it is in the mesh and completely	16	For diagnostic purposes, I don't
17	surrounded by the mesh, the contraction will pull.	17	well, I mean, first of all, I'm not sure if it can
18	So this is my interpretation as a pathologist.	18	be done. Second, I don't see diagnostic purpose,
19	If I measured what the strength, what	19	and I certainly wouldn't expect it to be done for
20	the force it produces in that specific section, no,	20	diagnostic purposes.
21	but I don't have to. Because my job is	21	BY MS. BYARD:
22	interpretation, and that is my interpretation.	22	Q. Are you familiar with something
23	Q. Okay. So in answering my	23	called "urodynamic testing"?
24	question, have you tested this yourself in humans,	24	A. Urodynamic is different.
25	in living humans, your answer would be, "no"?	25	Q. How so?
	D 202		
	Page 303		Page 305
1		1	
1 2	MR. ORENT: Objection.	1 2	A. Well, then they measure forces and
2	MR. ORENT: Objection. THE WITNESS: No. I mean, I explained	2	A. Well, then they measure forces and pressures to understand what's causing urinary
2 3	MR. ORENT: Objection. THE WITNESS: No. I mean, I explained to you that I interpret based on what we know about	2 3	A. Well, then they measure forces and pressures to understand what's causing urinary symptoms.
2 3 4	MR. ORENT: Objection. THE WITNESS: No. I mean, I explained to you that I interpret based on what we know about tissue reaction and general physiology of humans.	2 3 4	A. Well, then they measure forces and pressures to understand what's causing urinary symptoms. Q. And they measure the forces of
2 3 4 5	MR. ORENT: Objection. THE WITNESS: No. I mean, I explained to you that I interpret based on what we know about tissue reaction and general physiology of humans. BY MS. BYARD:	2 3 4 5	A. Well, then they measure forces and pressures to understand what's causing urinary symptoms. Q. And they measure the forces of various intraabdominal contractions, or the
2 3 4	MR. ORENT: Objection. THE WITNESS: No. I mean, I explained to you that I interpret based on what we know about tissue reaction and general physiology of humans. BY MS. BYARD: Q. Okay. You also write that:	2 3 4 5 6	A. Well, then they measure forces and pressures to understand what's causing urinary symptoms. Q. And they measure the forces of various intraabdominal contractions, or the detrusor muscle contraction
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	Page 306		Page 308
1	A. For my purposes, we are not doing	1	Q. Well, in a normal healthy person,
2	more than that as a pathologist. If it's done for	2	you wouldn't see pelvic organ prolapse to begin
3	any other diagnostic procedures, I'm not aware of	3	with, would you? That's an abnormal finding?
4	commonly used diagnostic tool which would use	4	MR. ORENT: Objection.
5	elasticity for a specific diagnosis.	5	THE WITNESS: Partially, it's a
6	Q. Well, researchers have looked at	6	relaxation, age-related; so what do you mean? I
7	the elasticity of virgin tissue compared to scar	7	mean, healthy younger individual, yes, this would
8	tissue, haven't they?	8	be a problem.
9	A. Well, that's research. Research	9	BY MS. BYARD:
10	and clinical practice are different areas, I	10	Q. Similarly, stress urinary
11	mean	11	incontinence is an abnormal finding, isn't it?
12	Q. So irrespective of whether it's in	12	A. Yes.
13	research or clinical practice, there are ways to	13	MS. BYARD: Okay, Doctor, I think we've
14	look at the relative elasticity of different types	14	reached a good stopping point for the night. I
15	of tissues?	15	thank you for your time.
16	MR. ORENT: Objection.	16	THE WITNESS: Thank you.
17	BY MS. BYARD:	17	THE VIDEOGRAPHER: This marks the end
18	O. True?	18	of media number four in today's proceedings in the
19	A. Yes. I mean, mostly for research,	19	deposition of Dr. Vladimir Iakovlev.
20	as I expect. Maybe there is a very limited amount	20	We are going off the record at 6:31 p.m.
21	of clinical applications, like for genetic	21	
22	conditions when there is not enough collagen or	22	Whereupon the deposition was suspended at 6:31 p.m.
23	something else, I mean, but	23	···
24	Q. Or with pelvic organ prolapse,	24	
25	too, where there are different types of collagen	25	
∠ ⊃	too, where there are different types of confagen	25	
<u> </u>		23	Page 309
	Page 307		Page 309
1	Page 307 present at different levels that lead to	1	Page 309 REPORTER'S CERTIFICATE
1 2	Page 307 present at different levels that lead to abnormalities in the structures of the pelvis?	1 2	
1 2 3	Page 307 present at different levels that lead to abnormalities in the structures of the pelvis? A. I don't think it is not. Pelvic	1 2 3	REPORTER'S CERTIFICATE
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1 2 3 4 5 6 7	present at different levels that lead to abnormalities in the structures of the pelvis? A. I don't think it is not. Pelvic organ prolapse is just by visual assessment and degree of prolapse. Q. Do you know how the presence of different types of collagen in the pelvic floor	1 2 3 4 5 6 7	REPORTER'S CERTIFICATE I, JUDITH M. CAPUTO, RPR, CSR, CRR, Registered Professional Reporter, certify; That the foregoing proceedings were taken before me at the time and place therein set
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	Page 310		Page 312
1	CERTIFICATE OF REPORTER	1	* * ERRATA SHEET * *
2	CANADA)	2	
3	PROVINCE OF ONTARIO)	3	NAME OF CASE: IN RE: BOSTON SCIENTIFIC CORP.,
4	,	4	PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION
5	I, Judith M. Caputo, the officer before whom the	5	MDL NO. 2326
6	foregoing deposition was taken, do hereby certify	6	DATE OF DEPOSITION: DECEMBER 17, 2014
7	that the witness whose testimony appears in the	7	NAME OF WITNESS: VLADIMIR IAKOVLEV, M.D.
8	foregoing deposition was duly sworn by me; that the	8	
9	testimony of said witness was taken by me in	9	PAGE LINE FROM TO
10	shorthand, using Computer Aided Realtime, to the	10	
11	best of my ability and thereafter reduced to	11	
12	written format under my direction; that I am	12	
13	neither counsel for, related to, nor employed by	13	
14	any of the parties to the action in which the	14	
15	deposition was taken, and further that I am not	15	
16	related or any employee of any attorney or counsel	16	
17	employed by the parties thereto, nor financially or	17	
18	otherwise interested in the outcome of the action.	18	
19		19	
20		20	
21		21	
22	Judith M. Caputo, RPR, CSR, CRR	22	
23	1 , , ,	23	
24	Commissioner for taking	24	
25	Oaths in the Province of Ontario	25	VLADIMIR IAKOVLEV, M.D.
	Page 311		Page 313
1	INSTRUCTIONS TO WITNESS	1	PROVINCE OF ONTARIO)
2		2	TORONTO REGION)
3	Read your deposition over carefully.	3	,
4	It is your right to read your deposition and make	4	
5	changes in form or substance. You should assign a	5	
6	reason in the appropriate column on the erratum	6	I, the undersigned, declare under penalty
7	sheet for any change made.	7	of perjury that I have read the foregoing transcript,
8	After making any changes in form or	8	and I have made any corrections, additions or
9	substance, and which have been noted on the	9	deletions that I was desirous of making;
10	following erratum sheet, along with the reason for	10	That the foregoing is a true and
11	any change, sign your name on the erratum sheet and	11	correct transcript of my testimony contained
12	date it.	12	therein.
13	Then sign your deposition at the end of	13	
14	Your testimony in the space provided. You are	14	
15	signing it subject to the changes you have made in	15	VLADIMIR IAKOVLEV, M.D.
16		1	·
	the erratum sheet, which will be attached to the	16	
17		16 17	
17 18	the erratum sheet, which will be attached to the		Subscribed and sworn to before me this
	the erratum sheet, which will be attached to the deposition before filing. You must sign it in	17	Subscribed and sworn to before me this Day of, 2014 at
18	the erratum sheet, which will be attached to the deposition before filing. You must sign it in front of a witness. The witness need not be a	17 18	
18 19	the erratum sheet, which will be attached to the deposition before filing. You must sign it in front of a witness. The witness need not be a notary public. Any competent adult may witness	17 18 19	Day of, 2014 at
18 19 20	the erratum sheet, which will be attached to the deposition before filing. You must sign it in front of a witness. The witness need not be a notary public. Any competent adult may witness your signature.	17 18 19 20	Day of, 2014 at
18 19 20 21 22 23	the erratum sheet, which will be attached to the deposition before filing. You must sign it in front of a witness. The witness need not be a notary public. Any competent adult may witness your signature. Return the original erratum sheet	17 18 19 20 21	Day of, 2014 at
18 19 20 21 22	the erratum sheet, which will be attached to the deposition before filing. You must sign it in front of a witness. The witness need not be a notary public. Any competent adult may witness your signature. Return the original erratum sheet promptly. Court rules require filing within 30	17 18 19 20 21 22	Day of, 2014 at
18 19 20 21 22 23	the erratum sheet, which will be attached to the deposition before filing. You must sign it in front of a witness. The witness need not be a notary public. Any competent adult may witness your signature. Return the original erratum sheet promptly. Court rules require filing within 30	17 18 19 20 21 22 23	Day of, 2014 at (City) (Province)

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